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# REPORT OF A WHO MEETING ON DRUG POLICIES AND MANAGEMENT: PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS

Madrid, Spain, 22–26 October 1984

WORLD HEALTH ORGANIZATION

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WHO MEETING ON DRUG POLICIES AND MANAGEMENT:
PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS
Madrid, 22-26 October 1984

Table of Contents


| | Page |
|---|---|
| I. INTRODUCTION | 1 |
| 1. Objectives of the meeting | 1 |
| 2. Opening of the meeting | 3 |
| II. BACKGROUND | 3 |
| 1. Action Programme on Essential Drugs and Vaccines | 3 |
| 2. Role of UNICEF | 4 |
| 3. UNIDO | 4 |
| III. PROCUREMENT AND FINANCING | 4 |
| 1. Procurement | 4 |
| 1.1 Procurement by individual countries | 4 |
| a) Open tender (national or international) | 4 |
| b) Restricted tender | 5 |
| c) Negotiated procurement | 5 |
| d) Direct procurement | 5 |
| e) Combination of alternatives | 5 |
| 1.2 Procurement through a UN agency | 5 |
| 1.3 Organizations operating internationally | 5 |
| a) Crown Agents | 5 |
| b) Non-Governmental organizations | 6 |
| c) Private corporation or private/public sector partnership | 6 |
| 1.4 Pool Procurement | 6 |
| 2. Financing | 7 |
| 2.1 Methods of financing | 7 |
| IV. RECOMMENDATIONS | 7 |
| V. ANNEXES | |
| 1. Agenda | 9 |
| 2. List of Participants | 10 |
| 3. Working papers | 13 |
| 4. List of Documents | 86 |


## I. INTRODUCTION

Large proportions of populations in developing countries do not have access at prese
to essential drugs: those drugs deemed as basic and most needed for the health care of
population. There are several reasons for this state of penury, including the
unavailability of the drugs in th [illegible] the inadequacy of procurement procedures, o
distribution system and its manag

At the same time, however, a [illegible] budgets is s
on the supply of drugs that may n [illegible] population.
total drug bill of developing cou [illegible] in the range
US$ 15-20 billion per annum. Mar [illegible] nge in using
limited financial and technical r [illegible] e above situa
and supplying essential rather th

Governments committed to an A [illegible] ecide upon an
implement activities appropriate [illegible] establishment
improvement of national drug poli [illegible] ational finan



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technical resources, training of manpower, and development of health care infrastructures are necessary requisites for successful implementation of essential drugs programmes at country level. Many countries have already adopted the concept of essential drugs and significant progress is being made towards the implementatin of their new drug policies.

The World Health Organization, through its Action Programme on Essential Drugs and Vaccines, aims to support Member States in ensuring coverage of their populations by a regular supply of a selected number of safe and effective drugs and vaccines of acceptable quality at the lowest possible cost to help achieve the goal of health for all by the year 2000 through primary health care. This objective is being carried out by WHO in collaboration with UNICEF and supported by other United Nations agencies, bilateral agencies, the pharmaceutical industries, consumer groups, and other nongovernmental organizations, to help developing countries committed to improvement in the supply and use of essential drugs and vaccines.

The present report concerns one of a series of meetings being convened by the Action Programme on Essential Drugs and Vaccines on the different aspects of drug policies and management.

## 1. Objectives of the meeting

A constellation of problems rel
resources represents a most severe
essential drugs programmes. The at
expertise to bring to bear on discu
The meeting would explore alternati
of problems on procurement and fina
develop technical guidelines at thi
analysis of alternatives in this co

## 2. Opening of the meeting

The meeting was opened by Dr F.
Director-General of the World Healt
Organization to the Ministry of Hea
acting as host to the meeting. Dr
respresentatives participating from
Fund (UNICEF), the United Nations I
Nations Conference on Trade and Tec
and of the Christian Medical Commis
institutions in Spain.

Dr Robert Grosse of the USA was
Jayawardene of Sri Lanka the Vice-C
Rapporteur, and Dr F. S. Antezana o

Four basic working papers were
Health Care Financing" by Robert N.
Perspectives: Procurement and Finan
(DAP/WP/PF/84.2), "Financing and Co
(DAP/WP/PF/84.3), and "Price Determi
Procurement Strategies for Essentia
these papers appear in Annex 3. Bri
the context of issues under discussi

"From the perspective of economi
international health scene in re
equity or fairness, with helping
objective of 'Health for All by
'Meeting Basic Human Needs'. Th
financing as matters requiring p
Alma Ata spoke of making essential health care 'Universally accessible...and at a cost that the community and country can maintain...'

"These two concerns are, of course, closely related. As countries expand health services to more of their population, additional resources are required. How these

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resources may best be mobilized and most effectively be deployed are questions that must be answered if the objective of health for all is to be implemented. The selection of primary health care as the strategy is a recognition that human and financial resource limitations must be used as elements in designing programs, rather than as excuses for failures.

"The recommendations of the Alma Ata Conference noted that 'the provision of drugs accounts for a significant proportion of expenditures in the health sector; and that the progressive extension of primary health care to ensure eventual national coverage entails a large increase in the provision of drugs...' This meeting on the procurement and financing of essential drugs addresses a critical aspect of the resource problems of making effective health services accessible to more of our populations. What drugs are procured, in what quantities, at what prices, and from what sources will influence the coverage, the design, and the effectiveness of a health delivery system from available resources. The quantity of those resources, their financing, will depend on household incomes, the revenues of government, foreign exchange availability, competing social, economic, and security needs, and on the organization of financing through budgetary, market and insurance mechanisms."(DAP/WP/PF/84.1)

"The development, production, and distribution of pharmaceuticals is a business, involving money, tangible products, and intangibles (notably information). It is a business whether conducted in the private sector or in the public sector, and whether carried out by one or more monolithic entities or by a series of small firms. Whether the business operates in a totally free market environment (at one end of the spectrum) or in the environment of a centrally controlled, planned economy (at the other end), is a political decision.

"As a business, the pharmaceutical enterprise is influenced by often rapidly shifting national and international macro trends and events over which most governments have little influence (e.g., those associated with technology, international politics, changing diagnostic and therapeutic regimens, consumer wants and needs, health care professionals). The same dynamic situation applies to the industry (or micro) factors such as effective demand, distribution systems, financing and procurement, competition, competitors, and rewards (including profits).

"Hence, any manager within the pharmaceutical supply system needs to continuously modify his or her own function's or department's internal activities in response to the external factors that over time will cause significant change in these activities. In short, the extent of professionalism at all levels of the pharmaceutical supply system is a critically important variable.

"The implication of this situation is that no static recipe can be developed, in generic terms, for a universally effective, strategic and tactical approach to procurement and financing of essential drugs. At best, again in my assessment, some general principles and guidelines--perhaps supported by examples and check lists--can be developed, based on 'real life' experiences and situations." (DAP/WP/PF/84.2)

"In the face of rising expenditure on pharmaceuticals in all countries, a number of measures to control and moderate this increase have been formulated. This paper sets out to review the measures which can be applied, together with the advantages and disadvantages, and to give a more detailed description of the Spanish experience, in order to highlight the factors responsible for drug demand, and the effects of the measures taken by the Spanish administration, and in particular, the contribution of the insured to drug prices.

"These consist of measures directed at attempting to reduce the quantity of pharmaceuticals consumed and the total value of expenditure on these products. There are three types of mechanism which have been applied, to a great or less extent, in different countries, and which can be summarized as measures affecting the patient. Each of these mechanisms has been expressed in a number of specific forms.

"The insurance organization tries to keep drug costs down by obtaining the product at the best price from producers and distributors. These measures can be grouped as follows: control of laboratory prices, restriction of promotion spending, control of distribution margins, and substitution policies." (DAP/WP/PF/84.3)

A number of selected country cases were prepared for presentation, and information documents provided by the Programme on Essential Drugs and Vaccines were available to participants. These references, together with several others, may be found listed in the bibliography in Annex 4.

## II BACKGROUND

### 1. Action Programme on Essential Drugs

From its early beginnings WHO has had a constitutional mandate concerning drugs, and its executive bodies have adopted a number of resolutions in this field.

In 1977 a WHO Expert Committee on the Selection of Essential Drugs proposed guidelines for establishing a list of essential drugs; a "model list" of approximately 250 drugs and vaccines was drawn up to serve as the basis for individual countries to establish their own lists, according to their health priorities. (The model list was reviewed and updated by an Expert Committee in 1979, 1982, and in 1984.)

Having considered the Director-General's progress reports on drug policies and management to the Thirty-first and the Thirty-second World Health Assemblies, that executive body adopted a resolution (WHA32.41) requesting that a special programme on essential drugs be established. The Action Programme on Essential Drugs was formally set up in February 1981. In this same year a UNICEF/WHO Joint Committee on Health Policy adopted a joint programme for supporting the provision of essential drugs for primary health care in developing countries.

The Action Programme's functions are both operational and managerial; together with advisers in WHO Regional Offices, it both helps set in motion and collaborates in many activities at the country level, world-wide, aimed at improving the availability and utilization of acceptable quality essential drugs at the lowest possible cost.

Despite widely differing social, political, and health care systems, in all countries drugs are in some way obtained, distributed, and used. A common feature of drug consumption in developing countries is that a large proportion are imported pharmaceutical products. At the same time, there is an endemic, critical shortage of foreign exchange currency. In a climate of competing demands for funding, a low priority for the health sector exacerbates the obstacles faced in meeting drug requirements. In addition, there is often a lack of synchronization of financial cycles resulting in gaps in the timing of national budget appropriations and foreign exchange allocations. This unbalanced economic situation of many developing countries is a source of continual preoccupation.

Prices paid by developing countries for imported pharmaceutical products can be several times higher than prevailing prices in international competitive markets. The reasons are many and varied and no single, standard answer can be cited. Lack of sufficiently large orders, "emergency" buying, and lack of effective market intelligence and international tendering experience are among the reasons.

### 2. Role of UNICEF

A UN specialized agency, UNICEF, has many country-level multisectorial projects and has a long experience in procurement of goods and services. UNICEF works closely with several WHO programme areas, and in national projects there is often a synergistic effect by UNICEF and WHO with their different functions and means of operation.

Substantial savings can be achieved in buying essential drug requirements by using procurement procedures which strengthen the buyer's position. It seems clear that with its experience and expertise, the available facilities of its packing and assembly centre (UNIPAC), in Copenhagen, and with its economies of scale, UNICEF can help countries realize substantial savings by procuring essential drugs on their behalf. This has proven to be the case, in practice.

As an example, an international tender on behalf of Tanzania commenced in 1983 for a three-year cycle. Prices in the second year of the cycle were again decreased and competition among bidders has been very strong. UNICEF drug procurement in 1984 has, in fact, shown some price reductions of 26% as compared to 1983.

Procurement by UNICEF of finished drug products (it also handles raw materials) concentrates on primary health care requirements. Its List of Indicative Prices for Essential Drugs, periodically updated, show prices which are generally substantially lower than from other sources and its international tenders have elicited wide responses from companies in as many as forty countries. While the total volume of essential drugs handled until now is still modest, the newly-expanded facilities at UNIPAC will allow a considerable increase in processing capacity and strong efforts to reduce lead-time for drug delivery will be made.

Its requirement for prepayment is a constraint to the use of UNICEF procurement by developing countries. This means that invoices must be paid in foreign exchange 6-8 months in advance of the receipt of the drug consignment--a requirement that can be exceedingly difficult to meet. The prepayment requirement arises from the fact that UNICEF does not have a reserve fund to use for these purposes and is thus unable to extend credit to the time the order is filled. A certain flexibility does, however exist; e.g., acceptance under certain circumstances of partial payment in local currency in countries where there are UNICEF projects (decisions are taken on a case-by-case basis). UNICEF is also seeking ways in which modifications in payment terms may be made.

3. UNIDO

UNIDO has established a series of continuing consultations between industrialised and developing countries in support of the Lima Declaration calling for an increased share by developing countries of total world industrial production, including pharmaceutical production. Wide disparities in prices of bulk drugs (pharmaceutical chemicals) and their intermediates and the complexity of issues relating to both availability and pricing has been among the concerns.

UNIDO has prepared a directory of sources of twenty-six selected pharmaceutical chemicals (see Annex 4) which will be gradually expanded to cover all pharmaceuticals included in the WHO Model List of Essential Drugs.

## III. PROCUREMENT AND FINANCING

The meeting discussed the working papers, and specific country cases were presented. There were extensive exchanges of views, ideas, and experience touching many aspects of the wide range of issues implicit in the areas of procurement and financing, including the alternative means of procurement. A certain amount of experience existing in some regions on pool procurement of essential drugs or vaccines was also described.

The discussions concerning financing outlined various methods which could be considered and emphasized the need to tailor the type of financing to the means of procurement, although this financial aspect was not specifically detailed.

### 1. Procurement

Procurement is but one element of the global system of supply of drugs to the population.

#### 1.1 Procurement by individual countries:

(a) Open tender (national or international)

Open tendering is a formal procedure by which quotations for the supply of a drug under its medical (generic) name are invited from any manufacturer or his representative, preferably on a worldwide basis, subject to the terms and conditions specified in the tender invitation.

- Generally for high value, large volume procurement.
- Obtains low prices but requires substantial planning.
- Requires stringent attention to quality assurance.

(b) Restricted tender

In a restricted tender also termed a closed bid or selective tender a limited number of suppliers are allowed to submit their quotations for the supply of a

drug under its medical (generic) name. Normally the number of suppliers is limited to ten or less.

- Time-saving, but may not provide the lowest price.
- Requires selection of suppliers.

(c) Negotiated procurement

In negotiated procurement, the buyer approaches a small number of selected potential suppliers and bargains with them directly to achieve specific price or service arrangements. Although the negotiation process is usually based on some form of competition among suppliers, it can involve negotiation with only one firm.

- Time-saving.
- Requires prior intelligence about suppliers and prices.

(d) Direct procurement

Direct procurement is direct purchase from a single supplier at his quoted price without previously requesting offers from other potential suppliers.

- This is the simplest method of procurement.
- There may be no alternative for some drugs under patent.
- Generally used for low volume items or emergency supplies.

(e) A combination of any of the above alternatives.

1.2 Procurement through a UN agency, e.g. UNICEF, WHO

- Responsibility for quality assurance, price competitiveness, a complete product range and services are available from one source.
- Flexibility with payment and acceptance of local currency.
- Continuity of operation with government endorsement.
- Non-profit basis of operation and responsible to government bodies.
- Oriented to the needs of the target groups.
- Country has no control over sources of supply.

1.3 Organizations operating internationally

(a) Crown Agents

- Charge high commission rates.
- Long delivery times.
- May have long established relationships with some countries.

(b) Non-Governmental organizations, e.g. Supply of Equipment to Charity Hospitals Overseas (ECHO), International Dispensary Association (IDA), etc.

- Non-profit basis of operation.
- Wide range of products.
- Service oriented.
- Limited flexibility with payments.

(c) Private corporation or private/public sector partnership

- High capital requirement.
- Should have a wide product range and be service oriented.
- Could provide a competitive alternative service to other agencies.
- Administrative flexibility.
- Would need to service its capital.

1.4 Pool procurement, e.g. on inter-regional, regional or sub-regional basis through TCDC (technical co-operation between developing countries).

- Requires political commitment between countries.
- Requires coordination within countries.
- Requires agreement on funding arrangements, including currency needs.
- Synchronization of procurement and financial cycles are necessary.
- Agreement is required on items and quantities.
- Agreement is required on facilities, orgnization and management.

In considering these alternative approaches, the relevance of the following factors should be considered:

- Coverage of essential drugs and vaccines (i.e., number of items).
- Inclusion of other drugs and vaccines.
- Inclusion of medical and surgical supplies.
- Available management and operational capabilities in the country.
- Saving of managerial effort, including budgeting.
- Quality assurance.
- Packaging and labelling.
- Logistics, including ration kits, delivery arrangements.
- Inventory control.
- Information.
- Services, including budgeting of requirements, training of health workers.
- Trading terms.
- Relationship with financial/funding options.
- Criteria for selection of manufacturers/suppliers (DANIDA/Tanzania tender).
- Product liability.
- Supply of active pharmaceutical ingredients in addition to formulated products.

2. Financing

Improving existing procurement mechanisms at domestic level particularly in the public sector, including improving the efficiency at the distribution and dispensing levels, are essential means for increasing drug availability within the same overall (foreign exchange) budget.

The value of the resources thus released needs to be maximized, including changes in priorities within the sector, e.g., in favour of essential drugs, as well as between different sectors, e.g., larger allocations for pharmaceuticals instead of other (consumer) goods.

One important aspect of improved efficiency is market intelligence and greater transparency of the market for various drugs, intermediates and raw materials, in particular for the essential drugs included in the WHO list.

The methods of financing need to be carefully adjusted to the methods of procurement, e.g., direct or indirect; the nature of customer, e.g., public sector of small or large countries; and the range of pharmaceuticals to be covered. Other specific elements may have to be taken into account, e.g., target populations like the children, the aged, the very poor, the very remote areas, etc., in which case the procurement system would have to be integrated with other forms of programmatic assistance or specific projects of cooperation programmes.

For the purposes of the meeting, the discussion concentrated on the international procurement level.

2.1 Methods of financing

There are a number of methods of financing that can be considered in light of the specific objectives to be attained. Several possibilities were discussed:

(i) Establishment of a commercial enterprise capitalized from a cross-section of financial sources (public and/or private entities) with working capital from commercial banks.

(ii) Intergovernmental agreements for the establishment of a public sector hard currency fund for procurement of essential drugs and vaccines. This agreement could also be used for the establishment of a revolving fund, which may introduce an additional element of flexibility for individual countries, in particular when coupled to a multi-country pool procurement scheme. The primary objective would be to make essential foreign exchange available at the right time for the procurement of essential drugs with repayment on, or after, delivery of drugs to recipient countries. At present, PAHO is operating an effective revolving fund for vaccines in support of the Expanded Programme on Immunization.

(iii) Arrangements were mentioned for bilateral and/or multilateral barter trade, which circumvented foreign exchange shortages.

(iv) In the longer term, establishment of a hard currency revenue-generating investment fund, the profits/interests of which would be utilized for procurement of essential drugs and vaccines.

(v) UNICEF, as part of its ongoing programmes, has already had an opportunity of ensuring the procurement of essential drugs for a certain number of developing countries. As a multilateral agency, UNICEF is able to accept mixed payments, including local currencies in specific cases.It has been able to achieve much lower prices although at present, the scheme suffers a certain number of rigidities, including the need to effect prepayments by recipients.

This could be resolved through the establishment of an essential drugs procurement fund, which would help bridge the various gaps in the timing of payments. Such a fund might also be useful in ensuring credit lines to the UNICEF/WHO.

IV. RECOMMENDATIONS

Several international forums have recognized that although some countries have established basic drugs supply systems and procurement mechanisms, there is still an imbalance in the supply of essential drugs to large segments of populations, especially in

the developing world. The meeting stressed that unless this gap between need and access can be reduced, the objective of making available essential drugs and vaccines in support of primary health care will not be achieved.

The meeting considered that efficient and economic procurement of essential drugs and vaccines, supported by adequate financing arrangements, are of utmost importance in meeting these objectives.

The meeting also considered that when making arrangements for the supply of essential drugs and vaccines, consideration should be given to the inclusion of medical and surgical supplies. Procurement of essential drugs cannot be viewed in isolation from other steps which need to be taken at national and/or international levels with respect to production, investment, trade, technology transfer, and other developmental efforts of the chemical/pharmaceutical industry in the developing countries.

The meeting recommends that:

(i) Existing international systems for the supply of essential drugs and vaccines be evaluated to determine the potential for increasing their scope of operations and efficiencies;

(ii) an examination be made of the practicality of making use of the International Federation of Pharmaceutical Manufacturers Association (IFPMA) offer for the supply of essential drugs in the context of existing procurement systems (at national and international levels);

(iii) a feasibility study be carried out to determine the practicality of establishing an international commercial enterprise to assist in meeting the objectives of the essential drugs programme;

(iv) the findings of these studies should be made known to Member States by WHO;

(v) the present UNICEF/WHO scheme should be financially reinforced to provide capital to allow UNICEF to proceed with requested procurement of essential drugs and vaccines without the need for prepayment by Member States prior to delivery; and

(vi) examination be made of the potentials of several financing mechanisms and sources both of a monetary and non-monetary nature.

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ANNEX 1

Meeting on Drug Policies and Management:

Procurement and Financing of Essential Drugs

Madrid, 22-26 October 1984

## Agenda

1. Opening (Election of Officers and Consideration of the Agenda)
   - 1.1 Opening Remarks
   - 1.2 Introduction
   - 1.3 Note from the Secretariat
2. Procurement of Essential Drugs (including Intermediate Substances)
   - 2.1 Different Forms of Procurement
   - 2.2 Mechanisms and Strategies
   - 2.3 Price Trends of Essential Drugs
   - 2.4 Standardization and Efficiency in Procurement
3. Financing
   - 3.1 Different Modalities
   - 3.2 National and International Financing Mechanisms
   - 3.3 Revolving Funds
   - 3.4 International Monetary System and Financing of Essential Drugs
   - 3.5 Other Financial Mechanisms
4. International Schemes for Procurement and Financing of Essential Drugs
5. Conclusions and Recommendations

ANNEX 2

Meeting on Drug Policies and Management:
Procurement and Financing of Essential Drugs

Madrid, 22-26 October 1984

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DAP/84.5
page 13

Working paper for

ANNEX 3.1

MEETING ON DRUG POLICIES AND MANAGEMENT:
PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS
Madrid, 22-26 October 1984

DAP/WP/PF/84.1

# SOME NOTES ON HEALTH CARE FINANCING

by
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CONTENTS

Page

1. Introduction . . . . . 2

2. Central Government Finance . . . . . 3

Table 1 - Central Governement Expenditures - Percent of GNP - 1981 . . . . . 4

Table 2 - Hypothetical Government Costs to Provide Comprehensive Human Development Services in Low-income Countries . . . . . 5

Table 3 - Taxes as a percentage of GNP . . . . . 7

Table 4 - Percentage of Taxes 63 countries with less than $1,000 per capita GNPs, 1972-76 . . . . . 7

Sources of Financing the Health Sector . . . . . 8

Table 5 - Health Care Expenditures by Source of Finance . . . . . 9

3. Expenditures on Drugs . . . . . 10

Table 6 - People's Republic of China Health Sector, Recurrent Expenditure, 1981 . . . . . 11

Table 7 - Private Health Care Spending, Selected Developing Countries . . . . . 12

Table 8 - Industrialized Market Economies - Expenditures on Pharmaceuticals as Percentage of Health Care Expenditures (1975) . . . . . 13

Table 9 - Drugs as Percentage of Health Expenditures in Developing Economies . . . . . 15

Table 10- Proportion of Imports and Local Production of Drugs in Various Developing Countries . . . . . 16

Table 11- Pharmaceuticals and Medicines . . . . . 17

4. Future Options . . . . . 18

References . . . . . 21

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Annex 3.1



## I. INTRODUCTION

From the perspective of economics, there have been two major changes in emphases in the international health scene in recent years. The first is the increased concern with equity or fairness, with helping the poor directly. This is exemplified by the objective of "Health for All by the Year 2000", and by the developmental goal of "Meeting Basic Human Needs". The second emphasis has been on issues of costs and financing as matters requiring professional and political priority. The Declaration of Alma Ata spoke of making essential health care "universally accessible...and at a cost that the community and country can maintain..."(1)

These two concerns are, of course, closely related. As countries expand health services to more of their population, additional resources are required. How these resources may best be mobilized and most effectively be deployed are questions that must be answered if the objective of health for all is to be implemented. The selection of primary health care as the strategy is a recognition that human and financial resource limitations must be used as elements in designing programs, rather than as excuses for failures.

The recommendations of the Alma Ata Conference noted that "the provision of drugs accounts for a significant proportion of expenditures in the health sector; and that the progressive extension of primary health care to ensure eventual national coverage entails a large increase in the provision of drugs..."(2) This meeting on the procurement and financing of essential drugs addresses a critical aspect of the resource problems of making effective health services accessible to more of our populations. What drugs are procured, in what quantities, at what prices, and from what sources will influence the coverage, the design, and the effectiveness of a health delivery system from

available resources. The quantity of those resources, their financing, will depend on household incomes, the revenues of government, foreign exchange availability, competing social, economic, and security needs, and on the organization of financing through budgetary, market and insurance mechanisms.

2. Central Government Finance

In the poorer countries public revenue (taxes, other domestic revenue and foreign assistance) usually is less than 20 percent of GNP; even middle income countries do not average much more. Table 1 presents average central government expenditures measured as percent of GNP by broad sector for developing and industrial economies. While health is identified separately, it should be noted that a large part of social security expenditures finance health care.

Expenditures other than on social programs (agriculture, infrastructure, debt service, defense, etc.,) commonly exceed 12 percent of GNP. Average allocations to social programs range from 2 percent for the poorest countries to over 7 percent of GNP for upper middle income developing countries.

While a few countries (Sri Lanka and probably China) have managed to provide essential services to most of their populations for less than 10 percent of GNP, Jacob Meerman of the World Bank estimated that providing adequate nourishment, primary education, health care, family planning, and water and sanitation to 95 percent of the population of low-income countries would take 11 to 21 percent of their GNP per year (seé Table 2).

The meeting of basic needs in health, nutrition, education, and water will mean, then,a very large increase of expenditures for most developing countries. Central government revenues have been viewed as their major source. But most developing countries are now probably taxing at close to their fiscal capacities

Annex 3.1



Table 1

Central Government Expenditures

Percent of GNP - 1981

| | Low-income economies | Lower middle-income economies | Upper middle-income economies | Industrial market economies |
|---|---|---|---|---|
| Total | 15.4 | 20.8 | 20.6 | 28.3 |
| Social sectors: | 2.1 | 4.8 | 7.2 | 16.5 |
| Education | 0.9 | 3.0 | 2.9 | 1.5 |
| Health | 0.4 | 0.9 | 1.1 | 3.2 |
| Housing and community amenities; social security and welfare | 0.8 | 0.9 | 3.2 | 11.8 |
| Other sectors: | 13.3 | 16.0 | 13.4 | 11.8 |
| Defense | 2.8 | 2.9 | 1.8 | 3.8 |
| Economic services | 4.0 | 5.5 | 5.6 | 2.8 |
| Other | 6.5 | 7.6 | 6.0 | 5.2 |

Source: Computed from World Bank, World Development Report, 1984, pp. 268-9.

Annex 3.1



Table 2

Hypothetical Government Costs to Provide Comprehensive Human Development Services in Low-income Countries (percentage of GNP)

| | Range |
|---|---|
| Adequate nourishment | 2-4 |
| Universal primary education | 3-5 |
| Health care, hygiene, family planning | 1-2 |
| Pure water and sanitation | 1-2 |
| Subtotal | 7-13 |
| Associated investment | 1-3 |
| Adjustment for underfunding of recurrent costs | 1-2 |
| Subtotal | 9-18 |
| Incremental costs of covering 85th to 95th percentile | 2-3 |
| Total | 11-21 |

Source: Jacob Meerman, "Paying for Human Development", Implementing Programs of Human Development, World Bank Staff Working Paper No. 403, July 1980, p. 124.

Annex 3.1



as determined by the pattern of their production, in which hard-to-tax traditional agriculture predominates, and by their generally weak tax administrations. Further, taxation of the poor may contribute to undernutrition or other negative effects on human development, as tax systems of developing countries are largely proportional rather than progressive in impact.(3)

Since the 1950s governments of developing countries have responded to pressures to mobilize resources for development. This has had two effects on financing. One, more resources have been drawn into the public sector via taxes for public investment. Tax to GNP ratios rose about 40% through 1976. (see Table 3). Much of this increase was the result of introducing income taxes and broad based sales taxes to supplement those on foreign trade (Table 4). The large percentage of GNP spent on food and the high proportion of the populations of low income countries which are in absolute poverty make their current tax performance on taxable households and firms comparable to those of the industrialized nations.

Since 1975, with oil prices rises and worldwide recession, tax ratios in oil-importing developing countries have not increased. Although some steps might be taken such as making taxes more progressive and reducing evasion and arrears, there appears little scope now for raising taxation. It has been suggested that expansion of the tax system as the primary mode of financing the social sector may now be largely foreclosed.(4)

A second effect of the pressure for development has been the underfunding of recurrent or operating expenses. With economic growth the goal, and investment in physical capital considered the means, public budgeting has been concerned with how to reduce current recurrent cost expenditure in order to maximize investment and growth. Plans, analyses, financing and scheduling have focused on investment projects, with recurrent costs of interest only insofar as they compete with investment financing. The consequence has been both pressure to hold down these expenditures and the lack of attention to their proper estimation. Correction of inadequacies are difficult in developing

Table 3

Taxes as a percentage of GNP

| | 1953-55 | 1972-76 | Percentage Increase |
|---|---|---|---|
| 7 low-income developing countries | 11.2 | 16.0 | 43 |
| 17 middle-income developing countries | 12.1 | 16.4 | 36 |
| Total (24 developing countries) | 11.8 | 16.3 | 38 |
| 15 developed countries | 26.2 | 36.2 | 38 |

Note: Taxes include social security taxes

Source: World Bank, World Development Report, 1980, p. 73.

Table 4

Percentage of Taxes
63 countries with less than
$1,000 per capita GNPs, 1972-76

| | |
|---|---|
| Income tax | 26.6 |
| Property tax | 1.9 |
| Foreign trade tax | 36.9 |
| Sales tax | 28.0 |
| Poll tax | 0.9 |
| Other taxes | 5.6 |
| Total | 100.0 |

Source: Alan Tait, et al., "International Comparisons of Taxation for Selected Developing Countries, 1972-76," International Monetary Fund, Staff Papers, March 1979.

countries where there is little ability to raise revenues quickly enough to supplement budgeted expenditures. Uncertainties of revenues and of operational needs has led not only to incremental budgeting (last year's budget plus perhaps a little more) but also to repetitive budgeting during the year, so that agencies cannot even count on being able to make all approved expenditures.(5) The recurrent budget will tend to protect personnel at the expense of drugs and other supplies.

In Mali, perhaps an extreme example, even with growth in the number of health facilities, the Ministry of Health budget for drugs remained 1.2 billion Mali Francs year after year. Despite this budget approval, the Treasury failed to pay the drug bills. When the French companies cut off sales, the French government agreed to deliver 1.2 billion Mali Francs of drugs per year, free, if Mali would repay debts to the private firms in the same amount.(6)

Sources of Financing the Health Sector

If central government revenues in most developing countries are not likely to be expanded anywhere near the amount required to implement programs for meeting basic human needs, alternative financing approaches need to be further explored.

In nearly all countries health care expenditures have been financed by drawing funds from varying combinations of main sources: 1) personal households; 2) charitable donations; 3) voluntary health insurance; 4) social security; 5) industry; 6) general public revenues; and 7) foreign aid.(7)

The sources of health care expenditures in international market and East European market economies are shown in Table 5. There is considerable variation. In some economies - France, West Germany, Italy and the Netherlands, public insurance is the major source. In others, Sweden, Australia, Canada, the United Kingdom and East Europe - government tax revenues dominate. Direct private payments and private insurance were the largest sources in the U.S., and a significant element in several others.

Annex 3.1



Table 5

Health Care Expenditures by Source of Finance
(percentages of total)

| | Government | Public Insurance | Direct and Private Insurance | Other |
|---|---|---|---|---|
| Industrial market economies: | | | | |
| Australia (1979-80) | 61.6 | - | 34.6 | 3.8 |
| Canada (1975) | 66.3 | 9.1 | 22.0 | 2.6 |
| France (1975) | 7.0 | 69.0 | 22.6 | 1.4 |
| West Germany (1975) | 14.6 | 62.5 | 17.8 | 5.1 |
| Israel (1978) | 40.0 | 3.5 | 48.0 | 8.5 |
| Italy (1975) | 23.8 | 67.5 | 8.7 | - |
| Netherlands (1974) | 15.1 | 56.0 | 27.3 | 1.6 |
| Sweden (1975) | 78.5 | 13.1 | 8.4 | - |
| Switzerland (1975) | 41.7 | 24.8 | 33.5 | - |
| United Kingdom (1974-74) | 87.3 | 5.0 | 7.0 | 0.4 |
| United States (1974-75) | 31.0 | 11.7 | 52.7 | 4.6 |
| East European nonmarket economies | | | | |
| USSR (1968) | 89.0 | 7.0 | 4.0 | - |
| Bulgaria (1973 | 96.0 | - | 4.0 | - |
| Czechoslovakia (1973) | 70.0 | 23.0 | 7.0 | - |
| GDR (1968) | 49.0 | 48.0 | 3.0 | - |
| Hungary (1968 | 48.0 | 46.0 | 6.0 | - |
| Poland (1973) | 70.0 | 13.0 | 16.0 | - |
| Romania (1968) | 81.0 | 1.0 | 18.0 | - |

Sources: Robert J. Maxwell, Health and Wealth (1981), p. 61;
Michael Kaser, Health Care in the Soviet Union and Eastern Europe (1976), p. 31.
World Health Organization Financing of Health Services, SHS/SPM/80.3, (Nov. 1979).
Commonwealth Department of Health, Australian Health Expenditure 1975-76 to 1979-80: an analysis, (1983), pp. 24-25.

In the people's Republic of China, state outlays were about 30 percent of the total health sector expenditure in 1981, labor insurance and production brigades supplied about 40 percent, while private outlays were a surprisingly large 30 percent (Table 6).

While our information is incomplete, there is evidence that in developing market economies private spending is a very large portion of total health care expenditures, amounting to over 80 percent in India, South Korea and Bangladesh (see Table 7).

These individual expenditures have been made largely in the private sector for traditional and nontraditional practitioners' fees, purchases from pharmacists and herbalists and transportation. It has been suggested that private resources may be available to support public services. Under the rubric of "community financing", it has been stressed that beneficiaries must share in the costs if basic health services are to be extended to all by the year 2000.

The most common forms of community support are voluntary labor and direct personal payments. Voluntary labor is useful chiefly for one-time construction costs, while direct personal payments place the financing burden on the sick and limit access to persons who can afford to pay. Community financing has not paid for supervison, logistical support or referral linkages. Recent studies suggest that community financing is, at best, only a partial solution to financing problems, and that it may be more difficult and less effective than reallocation of current resources.(8)

3. Expenditures on Drugs

There is uncertainty about the proportion that drugs and vaccines are of health care expenditures. Maxwell's study indicates that industrial market economies spend about 10-20 percent of total health care outlays on drugs,

Table 6

People's Republic of China Health Sector

Recurrent Expenditure, 1981

| | Million Yuan | Yuan p.c. | % Share |
|---|---|---|---|
| Ministry of Public Health | 3,274 | 3.31 | 23.1 |
| Ministry of Education | 148 | 0.15 | 1.0 |
| Government Insurance | 780 | 0.79 | 5.5 |
| Labor Insurance | | | |
| Compulsory | 3,300 | 0.34 | 23.3 |
| Voluntary | 1,100 | 1.11 | 7.7 |
| Production Brigades | | | |
| Barefoot Doctors | 485 | 0.49 | 3.4 |
| Health Aides | 60 | 0.06 | 0.4 |
| Rural Midwives | 18 | 0.02 | 0.1 |
| Cooperative Insurance | 474 | 0.48 | 3.3 |
| Individual | | | |
| Cooperative Insurance | 474 | 0.48 | 3.3 |
| Direct Outlays | 4,071 | 4.12 | 28.7 |
| Total | 14,184 | 14.34 | 100.0 |

Source: Ministry of Public Health

Annex 3.1



Table 7

Private Health Care Spending, Selected Developing Countries

| | Private spending as percentage of total |
|---|---|
| Afghanistan | 88 |
| Bangladesh | 86 |
| Botswana | 16 |
| Egypt | 41 |
| Ghana | 72 |
| Honduras | 63 |
| India | 84 |
| Pakistan | 63 |
| Philippines | 79 |
| South Korea | 84 |
| Sri Lanka | 40 |
| Sudan | 41 |
| Thailand | 66 |

Sources: Wayne Stinson, Community Financing of Primary Health Care,(1982); Adrian Griffiths and Michael Mills, "Health Sector Financing and Expenditure Surveys", editors, The Economics of Health in Developing Countries; R.Grosse, et al., Public and Private Health Care Expenditure in Egypt, 1982.

Annex 3.1



Table 8

Industrialized Market Economies

Expenditures on Pharmaceuticals as Percentage of
Health Care Expenditures (1975)

| | |
|---|---|
| France | 21.0 |
| Italy | 20.0 |
| West Germany | 17.9 |
| Netherlands | 14.3 |
| Australia | 13.3 |
| United Kingdom | 12.7 |
| Canada | 10.4 |
| Sweden | 9.0 |
| Switzerland | 8.5 |
| United States | 8.3 |

Source: Robert J. Maxwell, Health and Wealth, (1981) p. 78.

(Table 8) In developing countries the proportions are frequently larger, but vary substantially (Table 9). These data are of doubtful comparability, as some refer to nation-wide outlays, others to specific health programs. The variations are in part a function of the prices of inputs other than drugs. The large percentage for the People's Republic of China - over 10 billion yuan on drug production and distribution out of a total health care expenditure by government, insurance programs, and individuals of 14 billion yuan, likely reflects China's low wage rates for labor.

The economic costs of pharmaceuticals to developing countries are not fully indicated by expenditures in local currencies. Where foreign exchange is in very short supply, as it is in oil-importing developing countries, use of that scarce resource is more constrained than the same or even larger expenditures on locallly procured inputs such as labor (i.e., the shadow price or opportunity costs are higher). While a few developing countries such as China, Egypt, Brazil and India have large home industries, most developing countries import about 80 percent of drug consumption. (Table 10)

The significance of drug requirements for foreign exchange ought, however, be put into perspective relative to other demands. In 60 percent of developing countries studied, pharmaceuticals and medicines accounted for less than 2 percent of the value of imports (Table 11). In over 90 percent of the countries, drugs were less than 3 percent of imports.

The availability of hard currencies is determined by exports and capital flows. These will be related to economic activity and import restrictions in industrialized countries, interest rates and debt schedules, as well as by the willingness of developed countries to lend and invest overseas. But the availability of foreign exchange for imports of essential drugs may be most sensitive to domestic priorities and allocations.

Table 9

Drugs as Percentage of Health Expenditures
in Develping Economies

| | |
|---|---|
| People's Republic of China (1981)[a] | |
| current expenditures: | |
| Western Drugs | 49 |
| Traditional drugs | 9 |
| Total drugs | 58 |
| Egypt (FY 1980-81)[b] | |
| Government and public sector | 60 |
| Private payments | 43 |
| Total health sector | 53 |
| Danfa Project, Ghana (1975-76)[c] | 32 |
| Botswana, 4 clinics (1974)[d] | 21 |
| Dominican Republic, Rural Program of Basic Health Services (1976-79)[c] | 18 |
| Zaire, (c. 1980)[e] | |
| Urban health center | 45 |
| Rural Health Center | 17 |
| Ghana, selected institutions, Jasikan and Birim Districts (1975-76) drugs and stores[f] as pecent of medical costs | 67 |
| Indonesia - public expenditures[g] | 31 |

Sources:

a) Ministry of Health, PRC
b) R. N. Grosse, et al., Public and Private Health Care Expenditures in Egypt, (1982).
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g) G. Ferster, Financing the Health Sector in Indonesia,(1981).

Annex 3.1



Table 10

Proportion of Imports and Local Production of Drugs
In Various Develping Countries

| | Import % | Local Production % |
|---|---|---|
| Africa | | |
| Algeria (1976) | 81 | 19 |
| Chad (1978) | 100 | 0 |
| Egypt (1976) | 20 | 80 |
| Ethiopia (1977) | 84 | 16 |
| Ghana (1976) | 70 | 30 |
| Guinea (1976) | 84 | 16 |
| Morocco (1978) | 73 | 27 |
| Sidam (1977) | 90 | 10 |
| Tanzania (1977) | 95 | 5 |
| Tunisia (1977) | 80 | 20 |
| Asia | | |
| Afghanistan (1977) | 62 | 38 |
| India (1977) | 6 | 94 |
| Indonesia | 90 | 10 |
| Malaysia (1976) | 75 | 25 |
| Nepal (1976) | 84 | 16 |
| Thailand (1977) | 65 | 35 |
| Latin America | | |
| Argentina (1976) | 22 | 78 |

Source: Case studies on pharmaceutical industry in developing countries, prepared by UNIDO 1978.

Table 11

Pharmaceuticals and Medicines

| % of total imports | Number of Developing countries |
|---|---|
| Less than 1.0 | 24 |
| 1.0 - 1.9 | 35 |
| 2.0 -219 | 25 |
| 3.0 - 3.9 | 7 |
| 4.0 - 4.9 | 3 |
| 5.0 - 5-9 | 3 |

Source: International Monetary Fund, International Financial Statistics, 1982.

4. FUTURE OPTIONS

The increased costs resulting from expanding health services are likely to be compounded by the epidemiologic transition underway in many developing countries. As life expectancy at birth increases at it has by over 10 years in less developed regions in the last 25 years, circulatory diseases and cancer will be of greater concern. Known treatments for these will require much more expensive drugs and equipment than those used to prevent and control infectious diseases.

It seems unlikely that most poorer countries will be able to achieve full coverage of their populations in health and education according to their own standards exclusively through government finance. Other options include reallocating existing expenses, keeping costs down, and using resources other than national tax revenues.

The World Bank noted that:

> Public spending on human development can be increased by reallocating government revenue from less productive uses, including wasteful showcase projects, subsidizing inefficient enterprises and, so far as security considerations permit, military spending (which on average in East Asia, South Asia and the Middle East exceeds public outlays on education and health combined). Within human development programs there is often room to reallocate budget shares away from high-cost and less-urgent projects (such as urban hospitals and universities serving the relatively well-off) and toward more basic programs (such as primary health care and education).(9)

Coping with increased requirement for essential drugs as health service coverage expands requires minimization of costs. Costs are the products of both quantities purchased and prices.

The use of essential drug lists and rational inventory policies to avoid overstocking are steps to be taken in keeping quantities down. Procurement of generics, centralized purchasing, use of tenders, and hard bargaining with suppliers are needed to hold down prices. Local formulation of dosages from bulk purchases have reduced both expenditures and foreign exchange

requirements. It is less clear that local production, if small scale, would produce economies and assure quality at earlier stages of the production process. Arguments for local drug manufacture are frequently more related to the broader problems of reducing dependency and increasing national self-sufficiency than to cost reduction.

The production of many types of drugs is dominated by a small number of very large firms. The consequences of this market situation is that purchasers face both monopolistic pricing practices such as prices above marginal costs and price discrimination - different prices in different markets - and the fact that large corporations expand their sales by selling costs - advertising and manufacturers' representatives - rather than by price competition. (10) In many countries the drug industry concentrates its selling on physicians who usually have great weight in both governmental and private purchases of drugs. Countering these selling activities includes substituting for the information function of manufacturers' representatives and countering the medical professions's power. Increased social control over quantities as well as prices are required.

With regard to additional sources of financing, the increased use of charges to finance health services might take into account two matters. First, that private expenditures on drugs are a high proportion of health outlays in many countries, but usually do not make up a large proportion of household expenditures. Second, the urban hospitals render services largely to higher income populations, who could afford not only to cover their own costs, but possibly also to make payments at levels which could subsidize primary health care in peripheral areas. Charges in low-income rual areas reduce utilization and have high collection costs, frequently exceeding revenues.

Social insurance, a significant part of health care expenditures in

12230

industrialized countries and in China, may be an additional route for developing countries' financing of health services, but requires an economic base which may not be available where subsistence farming and informal employment are major economic activities. Insurance systems may be attractive in some countries because they may make possible the socialization of the payments for health care and at the same time use a private delivery system if that is considered more effective than a socialized delivery system. One danger is that insurance systems have concentrated health resources on the urban employed, a relatively well served portion of the population.(11)

Whether a country is in a position to expand its social insurance system or not, increased rationalization of drug procurement and increased bargaining power and control of selling activities on the part of the drug firms are steps to be considered.

These remarks are probably only too obvious generalizations. The important and hard work is the specification and implementation of such activities in particular countries.

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ANNEX 3.2

DAP/WP/PF/84.2

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

Working paper for

MEETING ON DRUG POLICIES AND MANAGEMENT:
PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS
Madrid, 22-26 October 1984

# PHARMACEUTICAL INDUSTRY PERSPECTIVES: PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS

by

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CONTENTS

| | Page |
|---|---|
| Background | 2 |
| Introduction | 3 |
| International Financing Practices | 4 |
| Trends in U. S. Distribution of Pharmaceuticals | 5 |
| Future Price Trends for Essential Drugs | 8 |
| Attachment 1: List of Most Common Problems in Procurement and Financing of Essential Drugs | 10 |
| Attachment 2: Matrix 1 - Conceptual Overview of International Loan Sources and Practices | 11 |
| Attachment 3: International Loan Profile | 12 |
| Attachment 4: Figure 1 - U. S. Ethical Drug Distribution System | 13 |
| Attachment 5: Hospital Pharmacists Satisfied with Drug Wholesaler Services, National Study Says | 14 |

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exprimées dans les articles signés n'engagent
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Background

This paper is an informal and unedited collection of personal thoughts and observations pertinent to the subject matter, and not the product of a research project. Nor is this paper an expression of views held or policies supported by the organization that employs me, SRI International, Menlo Park, California. I wrote the paper at WHO's request as a contribution to the forthcoming WHO-sponsored meeting in Madrid in October.

The objective of WHO's Action Programme on Essential Drugs and Vaccines is to support Member States in ensuring the regular supply of a selected number of safe and effective drugs and vaccines of acceptable quality at the lowest possible cost, in order to help achieve the goal of health for all by the year 2000.

Since all countries have more or less well developed pharmaceutical supply systems, my understanding of WHO's mission with regard to essential drugs is that the Organization must seek to identify ways in which existing supply systems can be improved with regard to operating efficiency, cost effectiveness, and patient/consumer reach.

The essence of that mission, as I understand it, is to ensure that a selected number of basic, or essential, pharmaceutical preparations are available to the rural poor in the developing countries. "Available" implies "reasonably easy economic and physical access" by the population to good quality pharmaceutical products and services--within the parameters of the governing national policies, including resource allocation priorities.

In recent years, much information has been developed with regard to the complexities of pharmaceutical supply systems and their intricate and delicate workings. A great deal of this published literature has focused on the pharmaceutical situation in the developing countries and two publications have dealt at length with strategic and operational perspectives, respectively, of the most critical elements of pharmaceutical supply systems.*

Furthermore, also in recent years, a number of demonstration projects have been undertaken and continue to be carried out in various parts of the developing world, notably Africa and the Caribbean. These projects and undertakings have had various objectives, among which two have received priority attention: in-country distribution, especially to rural areas, and product procurement, especially of dose-form preparations from foreign suppliers. In the ANCOM nations of South America, multi-nation collaboration is being attempted in the local production of active pharmaceutical substances (bulk medicinal chemicals).

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* Pharmaceutical Industry Perspectives: PHARMACEUTICAL SUPPLY SYSTEMS MANUAL (SRI International, 1978) and MANAGING DRUG SUPPLY, The Selection, Procurement, Distribution, and Use of Pharmaceuticals in Primary Health Care (Management Sciences for Health, 1981).

Finally, numerous conferences and meetings have been held throughout the world to further and support WHO's Essential Drugs mission during the past several years.

Thus, all barriers to fulfilling WHO's mission have probably already been identified, and all that can be said about the adequacy and inadequacies of pharmaceutical supply systems has probably also been said. In this paper, I hope to avoid undue repetition while recognizing that some points are so important that they must never be forgotten in any serious discussion of pharmaceutical supply arrangements; a number of these points are stated below.

## Introduction

The development, production, and distribution of pharmaceuticals is a business, involving money, tangible products, and intangibles (notably information). It is a business whether conducted in the private sector or in the public sector, and whether carried out by one or more monolithic entities or by a series of small firms. Whether the business operates in a totally free market environment (at one end of the spectrum) or in the environment of a centrally controlled, planned economy (at the other end), is a political decision.

As a business, the pharmaceutical enterprise is influenced by often rapidly shifting national and international macro trends and events over which most governments have little influence (e.g., those associated with technology, international politics, changing diagnostic and therapeutic regimens, consumer wants and needs, health care professionals). The same dynamic situation applies to the industry (or micro) factors such as effective demand, distribution systems, financing and procurement, competition, competitors, and rewards (including profits).

Hence, any manager within the pharmaceutical supply system needs to continuously modify his or her own function's or department's internal activities in response to the external factors that over time will cause significant change in these activities. In short, the extent of professionalism at all levels of the pharmaceutical supply system is a critically important variable.

The implication of this situation is that no static recipe can be developed, in generic terms, for a universally effective, strategic and tactical approach to procurement and financing of essential drugs. At best, again in my assessment, some general principles and guidelines--perhaps supported by examples and check lists--can be developed, based on "real life" experiences and situations.

Designing strategies, developing tactics, and taking steps to implement specific plans for the "optimal" procurement and financing of essential drugs require, at minimum, (a) specific country focus, (b) adequate intelligence about the workings of the country's present pharmaceutical

supply system, and (c) an effective combination of capable, dedicated, and honest individuals adequately supported by stable political will and commitment and by dependable monetary resources.

Prior to preparing this write-up, I asked Dr. F. Antezana to send me a brief statement of the core problems involved with procurement and financing of essential drugs. As is apparent from Dr. Antezana's response--see Attachment 1, List of Most Common Problems in Procurement and Financing of Essential Drugs--the problems are numerous, far reaching, and in many cases undoubtedly beyond any "quick fix" solution by either the public or the private sector.

These problems are only magnified when it is recognized that bringing essential drugs within reach of the rural poor in many cases would require expansion of the existing market economy and strengthening of the infrastructure.

With all these perspectives in mind, I thought it might be useful in the context of the forthcoming Madrid-meeting to set out some parameters for international financing practices, discuss some innovative trends in U.S. pharmaceutical distribution, and speculate a little about future price trends for essential drugs.

## International Financing Practices

Since my knowledge of the international world of finance is quite rudimentary, I was fortunate to obtain the assistance of Mr. Paul A. Masson, a senior consultant with considerable practical banking experience from years in South America and Asia; Mr. Masson is a member of SRI's Financial Industries Department.

We developed a rudimentary lending matrix shown in Attachment 2. It led us to the conclusions that two among several other critical problems with regard to the financing of essential drugs in the developing countries seem to be that as presently structured the transaction involved (a) is not self-liquidating--a particularly important concern for commercial bankers--and that it (b) is likely to have a relatively modest economic priority for national and supranational banks.

We hypothesize further that for supranational banks to become involved a specific social mandate must be issued by the bank governors. For national banks, financing this type of goods will require re-prioritization of national resource allocation goals. For private banks, profit or business diversification objectives can hardly be met.

As a possible further aid to the Madrid-discussions, a basic loan profile is included as Attachment 3. It has only been partially filled in to highlight some of the attending uncertainties.

Annex 3.2



Assuming that some kind of public/private sector financial collaboration could be worked out it might have the following configuration:

Loan Sum - US$25 m; Loan Term - 10 years, at $2.5 m per year.

| | Year | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Lenders | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| African Dev. Bank (US$12.5 m) | | | | | | X | X | X | X | X |
| U.S. Imp./Exp. Bank (US$7.5 m) | | | X | X | X | | | | | |
| Chase Manhattan (US$5.0 m) | X | X | | | | | | | | |

Any funding arrangement can probably be turned into a revolving type of fund--much like a personal credit card operates. Indeed, it may not be too far-fetched to state that financing essential drugs for the rural poor in the developing countries entails problems not unlike those that would apply to issuing a limited-purpose credit card to an indigenous person.

The preceeding comments are, by necessity, introductory. Lack of substantative information appear to prevent, at this point, any analysis in depth of the international financing options that might be available to cover essential drugs transactions with the developing countries.

## Trends in U.S. Distribution of Pharmaceuticals

Attachment 4 (Figure 1) provides a recent bird's-eye view of the U.S. distribution system for ethical pharmaceuticals (primarily legend or prescription products, narrowly defined as "pharmaceuticals"). The figure shows the type of participants and their relative size and growth over time in the US$11,000 million ($11 billion) U.S. market in 1981. In the context of this paper, two points are particularly noteworthy:

- Wholesalers have dramatically increased their share of the distribution volume, and

- Goverment is a minor participant (buyer, financier, and user/consumer) in the system.

In connection with the latter point, note that (a) the U.S. government only finances a small share (10%?) of U.S. consumption of Rx and OTC pharmaceuticals, (b) only one federal price scheme sets ceiling prices (based on market prices at retail acquisition level) for certain federally-financed Rx pharmaceuticals, and (c) efforts by states (notably California) to enter the retail distribution system through volume purchase schemes have all failed.

The average U.S. consumer probably pays about 85% out-of-pocket for his pharmaceutical product needs (Rx and OTC items). This consumer also demands improved physical, economic, and informational access to safe and effective pharmaceutical products and services. Under the current U.S. Administration, the preference is for stimulation of the competitive market mechanism to meet consumer needs and demands, rather than for government intervention at manufacturing or distribution levels in the price setting mechanism.

Let me now turn to the first point mentioned above, namely pharmaceutical wholesalers and their role in the distribution system.

Innovative applications of computers in data processing and keen awareness among leading pharmaceutical wholesalers of the electronic communications revolution have changed the U.S. wholesaling industry from a tired and ailing form of enterprise to one of the country's most dynamic and innovative service industries. In the process, a major restructuring of the industry is underway, and the concept of the total service wholesaler has emerged. Such wholesalers offer a multitude of services to retailers, cut overall distribution costs for manufacturers, and sharply reduce inventory and inventory management costs.

Customer services offered to retailers, now or in the near future, include in-store terminals for order entry linked to a main-frame computer at the wholesaler; price-sticker updates which allow the pharmacist to change prices based on daily or periodic computer print-outs; customer profiles of pharmaceuticals usage which allow for the storage and retrieval of drug interaction data; and data tracking for management information systems including third party billing, inventory control, year-end customer print-outs of pharmaceutical purchases for tax purposes and accounts receivable management.

Efficiency requirements are increasingly forcing the wholesaler's traditional customer, the independent pharmacy, to sign up for one or more wholesaler programs. To benefit optimally from these programs, the pharmacist must sometimes surrender a significant element of his product selection powers to the wholesaler--a situation that enables the wholesaler to bargain harder with suppliers for price and service concessions. Some of these arrangements are known as "voluntary chains" and wholesalers now often offer their own "private label" products to their customers.

Volume requirements have forced the wholesaler to aggressively seek new customers, and significant wholesaler inroads have already been made into the hospital business as well as into the chain store business. The hospital market has been particularly important in raising the wholesaler's awareness of the U.S. generic market trends and the profit potential of the generics business:

- Competitive bids for pharmaceuticals are solicited by large hospital buying groups from and negotiated direct with manufacturers.

Annex 3.2



- Bids are often solicited only for products on a restricted formulary that has been developed by the hospital buying group--with pressure from a cost conscious source ("the guy with 50,000 patients in his briefcase") often prevailing over a professional, therapy-oriented source (the physician).

- Wholesalers have entered this direct manufacturer-hospital relationship by undertaking to keep inventory for the two parties at a cost that neither of them can match. Thus, a triangle has been created in which the wholesaler is designated "prime vendor."

- Wholesalers compete vigorously to obtain "prime vendor" status since that is now the funnel into virtually all the nation's nonprofit hospitals (U.S. antitrust statutes prevent the "prime vendor" system from being used among for-profit hospitals).

- An estimated 60% of all hospital purchases of "pharmaceuticals" (this term includes products that are excluded from SRI's pharmaceutical universe, e.g., I.V. solutions, blood and blood fractions, anesthetic gasses)--a US$3.5 billion market in 1983--is now done via wholesalers and is based on competitive bids.

Under the "prime vendor" system, the wholesaler typically supplies the hospitals in the buying group with goods from his normal inventory, most of which has been purchased for the retail trade. Since the contract hospital price is lower than the retail price, a "charge-back" system between wholesaler and manufacturer has been established. While product diversion via the "prime wholesaler" remains a potential problem, so far it has been a manageable one.

Finally, a copy of page 35 from "Wholesale Drugs Magazine" (Aug/Sep 1984) is included as Attachment 5. That page contains two tables with noteworthy information about the role of wholesalers in the U.S. hospital pharmaceutical supply system. It is particularly significant, in my opinion, that "competitive pricing" is of secondary concern to hospital pharmacists.

Can the U.S. wholesaler experience and the "prime wholesaler" concept be a model for adaption to the distribution of pharmaceuticals in the developing countries?

Pursuing this thought further, what is the feasibility of establishing one or more public/private sector international pharmaceutical wholesaling corporations with the specific charter of providing certain pharmaceutical products and pharmaceutical supply systems services to specified developing countries and/or companies and government agencies in these countries? As an analogy, is it appropriate to compare the pharmaceutical public sector in developing countries to the U.S. hospital market segment, and the private sector to the U.S. retail pharmacy segment?

If further inquiry suggests affirmative answers to these questions, then the various issues pertaining to the feasibility of implementation of such a "chartered international pharmaceutical wholesaler" scheme can perhaps be more readily discussed in practical terms.

From another strategic perspective, one would also need to examine whether in the context of macro and micro environmental developments and trends the mid-1980s appear to be a good time to undertake such an initiative, specifically would such an enterprise have a reasonable chance of becoming a viable enterprise?

## Future Price Trends for Essential Drugs

Overall, until the late 1980s, I expect price stability to prevail for most of the currently off-patent compounds and that the price level for compounds facing patent expiry in the near future will rise in the short term and then decline, in some cases perhaps even significantly. A few attending statements may be useful in this context.

- A critical variable is always the new product outlook, for the industry generally and for specific individual companies.

- With the development of a viable (i.e., profitable) market for generics in the United States during the past 3-4 years, the essential drugs concept has proved workable in the world's largest developed country. Competitive market forces rather than direct government coercion and market place intervention/participation have brought about this situation.

- Rx-to-OTC switches will tend to enhance competition and lower total consumer acquisition cost. Simultaneously, consumer awareness of pharmaceutical prices is likely to grow.

- The research-intensive pharmaceutical industry is under great financial pressure, and the leading firms have become highly discriminative in their selection and pursuit of new product investment projects. During the past half dozen years, I estimate that the average new (pioneer) product has not been as profitable an investment as merely putting the money in the bank.

- Cost/benefit judgements made at the drug selection and therapeutic use stages appear to be gaining increasing importance over risk/reward judgements made for new (pioneer) product investments ~~made~~ in corporate board rooms in USA and Europe. This means that in many cases price premiums for new products may be smaller than in the past.

- Most of the large pharmaceutical multinational corporations have or are in the process of adjusting to--and selectively participating in--a pharmaceutical market worldwide that is featuring large consumer-driven market segments.

Annex 3.2



- Quality differences (real and perceived) may soon emerge in the essential drugs (or generic drugs) business, and a 2-tier quality structure--with significant price differentials--may become a normal market feature. "Old" versus "New" drug delivery systems are expected to cause this quality differential in the safety and effectiveness of otherwise identical or similar drug compounds.

- Will consumers in the developed world gradually accept the existance of quality and cost differentials in the health care/pharmaceutical fields? Such differentiation is generally accepted for other basic consumer needs (food, shelter, clothing, education, transportation).

- Will product (i.e., dose-form specialties) life cycles tend to increase? Will compound life cycles follow a pattern different from that of dose-form specialties?

- Each essential drug compound competes in its own unique competitive environment. Therefore, the essential drugs business is really a collection of individually distinct businesses.

One last thought for this paper. In seeking to foster or establish an effective international essential drugs business, one would probably be well advised to try to understand the thinking of both marketing managers (product managers, country managers) in large pharmaceutical multinational corporations as well as in smaller generics firms and purchasing agents and managers in large pharmaceutical wholesaling companies.

# LIST OF MOST COMMON PROBLEMS IN PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS

- Appraisal of drug needs for national health services.
- Lack of information on sources of reliable suppliers at world level.
- Convertibility of local currencies into hard currency.
- Time gaps in availability of financial resources, especially foreign currency, and need to procure drugs.
- International monetary system and interest rates to finance short-term operations--one to two years.
- Priorities in economic planning regarding health.
- Financial management at country level.
- Lack of access of several developing countries to international financing systems.
- Size of order at institutional and national levels in individual countries--especially the smaller ones.
- Geographical and operational divisions by zones in countries of the pharmaceutical industry--multinationals--complicates the access to alternative sources of supply.
- Uncoordinated procurement by institutions and countries--list of products, specification terms for procurement and financing.
- Cost sharing versus "free" services.
- Management of drug supply systems.

Annex 3.2



Attachment 2

MATRIX 1

CONCEPTUAL OVERVIEW OF INTERNATIONAL LOAN SOURCES AND PRACTICES

| Selected Lending Criteria | Sources of Loans (1) Supra-national | National Government | Private Banks |
|---|---|---|---|
| Length of Loan | Long (15-20 yrs) | Medium (5-7 yrs) | Short (1-3 yrs) |
| Size of Loan | Large ($10-$300M) | Medium ($1-50M) | Small ($100K-$20M) |
| Expected Monetary Return (2) | Low | Moderate | High |
| Collateral (3) | None | Political/ Commercial | Tangible Assets |
| Expected Political Benefit (4) | High | High to Medium | Low to Nil |
| Source of Loan Repayment (5) | Gvt. income or taxes | Project and Company Revenues | Self-liquidating transaction |
| Type of Loan (6). | Project | Hard Goods | Hard Trade |

Explanations

(1) Supranational banks include I.B.R.D., Asian, and African D.B. National government banks include export/import banks, trusts, and project/program financing institutions. Private banks are privately and publicly held merchant (commercial) banks and export/import financing houses.

(2) Monetary return is measured in both absolute income and profitability to lender.

(3) National government banks may extend loans to achieve political good-will or improve export or import trade or dominate a strategic business.

(4) If "political benefit" is interpreted to include strategic objectives for private banks, the score for this criterion may occasionally be "high" rather than "low to nil." Both defensive and offensive strategic objectives may underlie such a posture by a private bank.

(5) "Self-liquidating transactions" cover finished goods that can be readily resold or raw materials that find ready use in industry.

(6) "Project" loans are "hard" (infrastructural projects such as roads, dams) or "soft" (management development, education). "Hard Goods" are agricultural or industrial machinery, bricks and mortar installations (factories, hospitals). "Hard trade" involve goods that can be consumed over a short period by consumers or by industry (consumer goods, grain, raw materials).

## INTERNATIONAL LOAN PROFILE

| | |
|---|---|
| Principal Sum: | US $ 25 - $ 100 million |
| Purpose: | Procurement of essential drugs from world-wide sources. |
| Use of Goods: | Human disease control and health enhancement among the rural poor in selected developing countries. |
| Borrower: | A public/private sector consortium, "Compassion, Inc.," Lichtenstein. |
| Party Responsible for Repayment: | Secretariat, The United Nations, New York (USA) |
| Revenue Source of Repayment: | o Sale of drugs financed (65%)<br>o Tax on U.N. membership fees (15%)<br>o General revenues of WHO, Geneva (5%)<br>o IFPMA contribution (5%)<br>o Donations, gifts, and grants from public and private sources (10%) |
| Collateral: | o Undistributed drugs<br>o Government guarantees<br>o Industry commitments |
| Repayment Terms: | |
| Grace Period to 1st Payment: | |
| Interest Rate: | |
| Loan Fees: | |
| Etc., Etc. | |

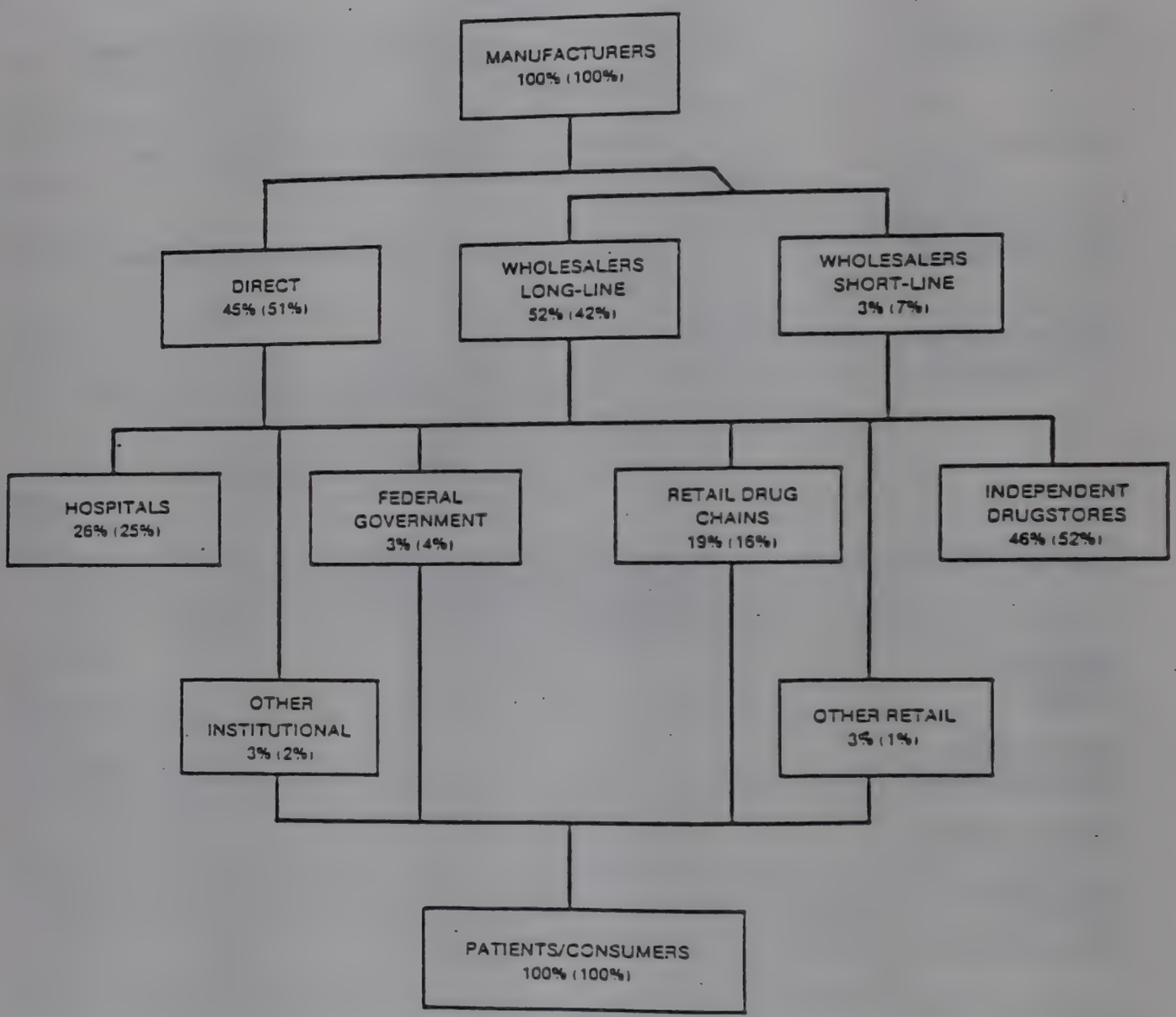
Annex 3.2



Attachment 4

Figure 1

U.S. ETHICAL DRUG DISTRIBUTION SYSTEM
Estimated Dollar Market Share at Manufactuer's Level
1981 (1976)




Source: Pharmaceutical Industry Perspectives: THE UNITED STATES IN THE 1980--NEW LEADERSHIP! (SRI International, May 1982).

# Hospital Pharmacists Satisfied with Drug Wholesaler Services, National Study Says

The results of a national study indicate that hospital pharmacists are satisfied with the services provided by their primary drug wholesalers.

The study, conducted by Wilson O. Allen of Baptist Memorial Hospital in Memphis, Tenn., and Dr. Kenneth B. Roberts of the University of Tennessee College of Pharmacy, was conducted in early 1983 and utilized data collected from 952 hospitals.

The objective of the study was to measure the importance of wholesaler services to hospital pharmacists and the satisfaction of hospital pharmacists with their services. In nearly every case, wholesaler services were reported to be either important or essential.

Of the 952 respondents, seventy percent rated four of the wholesalers' services essential. They were 1) stocking of injectable pharmaceuticals, 2) high service levels, 3) stocking of unit-dose pharmaceuticals and 4) competitive pricing.

In descending order of importance, the five most valued drug wholesaler services were 1) high service levels, 2) stocking of injectable pharmaceuticals, 3) stocking of unit-dose pharmaceuticals, 4) competitive pricing and 5) bid and contract prices from manufacturers available through drug wholesaler (Table 1).

Those services at the other end of the spectrum — those which were not essential to the pharmacists — included 1) list-less pricing, 2) frequent calls by wholesaler representatives and 3) specially trained representatives to work with pharmaceutical buyers.

According to the results of the study, most respondents were satisfied with wholesaler services. Those services receiving the highest satisfaction ratings were 1) no minimum order requirements, 2) pricing stickers with merchandise and 3) daily delivery service (Table 2).

The greatest dissatisfaction among the pharmacists included 1) inventory management report, 2) emergency delivery of prescription items and 3) list-less pricing system.

The service rated most important by respondents, high service levels, ranked fifteenth in the satisfaction ratings. Stocking of injectable pharmaceuticals was the second most important service and ranked as the fifth service with which respondents were most satisfied. This was the only service ranking within the top five positions for both importance and satisfaction.

"While the professional practice concerns of hospital pharmacists are radically different from those of the community practitioner," the study cited, "one overriding concern of all pharmacists is the management of

**TABLE 1**
**DRUG WHOLESALER IMPORTANCE RATINGS**

| SERVICE | RANK |
|---|---|
| Few out-of-stocks, i.e. high service levels | 1 |
| Stocking of injectable pharmaceuticals | 2 |
| Stocking of unit-dose pharmaceuticals | 3 |
| Competitive pricing | 4 |
| Bid and contract prices from manufacturers available through drug wholesaler | 5 |
| Daily delivery service | 6 |
| No minimum order requirements | 7 |
| Frequent microfiche or price catalog with price changes | 8 |
| Prompt crediting for delivery errors | 9 |
| Cost-plus pricing system | 10 |
| Frequent pickup of return merchandise | 11 |
| Emergency delivery of prescription items | 12 |
| Electronic order entry system | 13 |
| Pricing stickers with merchandise | 14 |
| Monthly report of controlled substances purchased | 15 |
| Same day delivery service | 16 |
| Periodic product movement report showing utilization for each product | 17 |
| Inventory management report | 18 |
| Frequent calls by wholesaler representative | 19 |
| Shelf labels | 20 |
| Specially trained representatives to work with pharmaceutical buyer | 21 |
| List-less pricing system | 22 |

**TABLE 2**
**DRUG WHOLESALER SATISFACTION RATINGS**

| SERVICE | RANK |
|---|---|
| No minimum order requirements | 1 |
| Pricing stickers with merchandise | 2 |
| Daily delivery service | 3 |
| Electronic order entry system | 4 |
| Stocking of injectable pharmaceuticals | 5 |
| Cost-plus pricing system | 6 |
| Stocking of unit-dose pharmaceuticals | 7 |
| Frequent microfiche or price catalog with price changes | 8 |
| Competitive pricing | 9 |
| Shelf labels | 10 |
| Same day delivery service | 11 |
| Monthly report of controlled substances purchased | 12 |
| Prompt crediting for delivery errors | 13 |
| Bid and contract prices from manufacturers available through drug wholesaler | 14 |
| Few out-of-stocks, i.e. high service levels | 15 |
| Frequent calls by wholesaler representative | 16 |
| Frequent pickup of return merchandise | 17 |
| Periodic product movement report showing utilization for each product | 18 |
| Specially trained representatives to work with pharmaceutical buyer | 19 |
| Inventory management report | 20 |
| Emergency delivery of prescription items | 21 |
| List-less pricing system | 22 |



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MEETING ON DRUG POLICIES AND MANAGEMENT:
PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS
Madrid, 22-26 October 1984

# FINANCING AND CONTROL OF PHARMACEUTICAL SPENDING

by

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Rough Draft, Madrid, July 1984

CONTENTS

| | | Page |
|---|---|---|
| 1. | OBJECTIVES | 2 |
| 2. | POLICIES FOR THE CONTAINMENT OF PHARMACEUTICAL SPENDING | 2 |
| 1. | DEMAND POLICIES | 2 |
| 1.1 | Measures affecting the physician | 2 |
| 1.2 | Measures affecting the products | 3 |
| 1.3 | Measures affecting the patients | 4 |
| 2. | POLICIES BEARING ON SUPPLY | 5 |
| 2.1 | Control of laboratory prices | 5 |
| 2.2 | Ban or restrictions on promotion | 5 |
| 2.3 | Control of wholesale and/or retail distribution mark-up | 6 |
| 2.4 | Substitution policies | 6 |
| 3. | PHARMACEUTICAL DEMAND BY THE SPANISH SOCIAL SECURITY SYSTEM, WITH SPECIAL REFERENCE TO PRESCRIPTION CHARGES | 6 |

* This document has been translated from Spanish but is reproduced in English only for the meeting.

** María del Mar Mediano and Rafael Cortes, economists, have collaborated in the preparation of this paper. We have also been helped, particularly in the drafting of Sections 1 and 2, by the internal documents of the Working Group for the Establishment of a New Pharmaceutical Price System set up in the Department of Pharmacy and Health Products of the Ministry of Health and Consumer Affairs in Spain by Humbert Arnes, Carlos Corea, Maria Antonia Hurtado, Pedro Lobato, Felix Lobo, Antonia Luaces, Peter O'Brien, Julio Seguara and Jose Antonio Zamora.

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## OBJECTIVES

In the face of rising expenditure on pharmaceuticals in all countries, a number of measures to control and moderate this increase have been formulated. This paper sets out to review the measures which can be applied, together with the advantages and disadvantages, and to give a more detailed description of the Spanish experience, in order to highlight the factors responsible for drug demand, and the effects of the measures taken by the Spanish administration, and in particular, the contribution of the insured to drug prices.

## POLICIES FOR THE CONTAINMENT OF PHARMACEUTICAL SPENDING

The objective of containing pharmaceutical spending should observe the constraints that the policies pursued should not adversely affect the health level of the population and should not obstruct the development of a local pharmaceutical industry. With this in mind, a number of steps have been taken in all countries, involving one or more measures which can be classified as follows:

1. Demand policies
2. Policies bearing on supply.

### 1. DEMAND POLICIES

These consist of measures directed at attempting to reduce the quantity of pharmaceuticals consumed and the total value of expenditure on these products. There are three types of mechanism which have been applied, to a greater or lesser extent, in different countries, and which can be summarized as measures affecting the patient. Each of these mechanisms has been expressed in a number of specific forms:

### 1.1 Measures affecting the physician

These are designed to impose some restriction on the amount (or the value) of drugs prescribed by doctors and charged to the organization administering health insurance. These measures are justified by the inherent characteristics of the pharmaceuticals market, in which it is the doctor (who prescribes), and not the consumer, who decides upon the product and the quantity to be consumed. The following measures have attempted to achieve this end:

Transparency lists: these consist of lists of drugs with a purely informational content, for the purpose of making doctors aware of the cost of their prescriptions. In these lists, the various different products which can be used for the same treatment are compared as to technical characteristics and prices. Since there are a great many brands on the market, it is often materially impossible for doctors to be familiar with all or most of them, and it is even more difficult for them to know their prices. These lists provide information to help in the selection of the least expensive of a number of similar products.

At the end of the 1970s official "transparency lists" were drawn up in the Federal Republic of Germany. At the present time, the Swedish Board of Health[1] is proposing to publish lists of comparative prices which will keep doctors continuously up to date with the considerable differences in prices.

There are other, similar measures, such as guides to drug therapy, an officialized vade mecum, or the preparation of technical information sheets, used to provide controlled information. In this connexion, reference can be made to the United Kingdom, where information sheets and other publications are used to try to keep doctors informed about the economic aspects of prescription.[2] In Spain, a monthly publication is issued free of charge with the aim of providing doctors and pharmacists with objective information.[3]

Control of prescriptions: this is based on each doctors' prescribing habits, and the use of corrective measures. Methods of control have varied considerably from one country to another, and we shall therefore look at the most significant.

Annex 3.3



In the United Kingdom, efforts are made to persuade doctors to prescribe economically. Those whose prescription costs exceed the average for their area by more than 25% are visited by a DHSS official, who discusses their prescription costs and tries to persuade them to use other, cheaper products, or to prescribe fewer drugs.[4]

A system of medical profiles has been set up in France,[5] as a means of identifying those doctors whose prescription costs are abnormally high and requiring them to justify their practice to a professional body.

In the Federal Republic of Germany, control of prescription has developed through collective negotiations between the health authorities and the medical profession. Treatment schedules for the most common diseases have been developed, and doctors whose prescribing exceeds the negotiated limits have to explain this discrepancy to a committee of physicians. If their explanations are repeatedly unsatisfactory, sanctions may be imposed.

In Spain, statistical methods of control of prescription have been established very recently; previously, there were restrictive procedures (endorsement) of a bureaucratic nature and without practical effects.[6] At present, procedures basically involve giving information to the biggest prescribers. To take this further, a better system would be the establishment of individual prescribing profiles for each doctor at regular intervals, providing him with the list of his prescriptions so that he can himself review his prescribing activities.

Measures for the control of prescription have the disadvantage of the high cost of the information processing involved, and also the resistance of doctors' professional associations to their implementation.

## 1.2 Measures affecting the products

These measures take the form of a list or lists of products which are wholly or partly reimbursed by the insurance organization. These lists are related to the contribution of the insured to the cost of the drug, or the "prescription charge", since very often there are different scales of contribution for each list of products. The types of measures applied have been the following:

Single positive restrictive list: a list of prescribable products which may be charged (wholly or partly) to the insurance organization. Such lists are designed to restrict access to certain products (e.g. expensive items), to furnish additional information on the most attractive products and prices, and to alter patterns of consumption.

As an example of a single list we may cite the Spanish "Petitorio" (Pharmacopoeia) which was legally in force between 1954 and 1967, although its usefulness in fact declined in 1965.

Several positive lists with administrative restrictions: there is differentiation between products which are included in different lists, with different procedures for the prescription of each of them. The aim is to restrict access to certain products and to alter the pattern of consumption, encouraging the prescription of some products and discouraging the prescription of others.

Negative lists: lists of products which may not be prescribed and charged to the insurance organization. "Luxury" or "comfort" products are usually excluded. For example, in the Federal Republic of Germany,[7] reimbursement of slimming, anabolizing, rejuvenating and fortifying products and tonics is excluded, as well as vitamin preparations except when they are prescribed to correct a deficiency.

The introduction of lists meet with resistance mainly on the part of industry, and to a lesser extent from doctors and pharmacists.

1.3 Measures affecting the patients

The most frequent measure is the contribution of the insured to the cost of drugs, euphemistically known (in Spanish) as the "ticket-moderador" (prescription charge).

The introduction of this measure is aimed at obtaining a contribution to the financing of drug provision, and at attempting to reduce demand and alter patterns of consumption. It must be pointed out that in view of the procedure for the prescription of drugs, the patient's contribution should not be expected to hold back demand, which depends on the prescriber (doctor), unless the consumer were to find the cost too much and do without the drugs prescribed by the doctor, which would be undesirable. The only effect might be to mitigate the pressure of patients on doctors for certain prescriptions, and this would only operate at the lowest sales levels. In short, it can be said that this is basically a financial measure, with some effects on consumption, whose desirability is open to a broad measure of doubt.

The contribution may be the same for all products, or it may be differentiated. In fact, three types of prescription charge can be distinguished, depending on the way the contribution is determined:

(a) Fixed contribution: a predetermined, fixed amount which is the same for all products, is paid for each item.

A single fixed prescription charge exists, inter alia, in the Federal Republic of Germany and the United Kingdom, although in the latter country it is not paid in respect of about 75% of prescriptions, since there is a wide range of exemptions (children under sixteen, men over 65 and women over 60, pregnant women or women with children under the age of one, people with low incomes or chronic diseases).

(b) Percentage of the price which varies depending on the type of product: the insured pays the pharmacist a percentage of the price, depending on the product. In France,[8] the insured pays the pharmacist the full cost and later obtains reimbursement of part of the cost. For most specialities, 70% of the cost is refundable, but for those which are particularly expensive and for which there is no substitute 100% is refundable, while only 40% is refunded for products for complaints or conditions which are not recurrent or serious. This picture is completed by exemption from charges for situations of a personal nature (occupational accidents or maternity) or certain diseases (list of serious diseases).

The Italian case is a combination of the two types of measures already described, since the "Catalogue of Medicines" contains three lists: one with no contribution by the beneficiary, the second with a fixed charge, and the third with a contribution comprising a fixed charge plus a percentage of the price.

(c) Contribution which varies according to the price of the product: a series of price steps is established, for each of which the patient's contribution may be a fixed amount or a given percentage.

As an example of the first case, the system in force in Italy[9] in 1982 stipulated a contribution of 200 lire if the price was less than 1,000 lire, 400 lire if the price was between 1,000 and 3,000 lire, and 600 lire if the price was over 3,000 lire. For the second type, the Swedish system[10] may be cited: in 1984, for most products, the patient pays 100% of the price up to 20 kronor and 50% of the cost for products between 20 and 80 kronor, while the maximum contribution is 50 kronor.

From these examples it can be seen that it is difficult to find a "pure" system of prescription charges, since combinations of various procedures usually occur in combination with lists of products.

In general, the drawbacks of product-related measures lie in the insensitivity of price to demand, which means that they do not much reduce consumption, but are rather of a financial nature. It has also been pointed out that this is a regressive method, since it adds a burden to consumption, in this case, consumption by the sick. Finally, problems of

deterioration in the doctor-patient relationship have been reported, when the patient has tried to get the doctor to alter his diagnosis or to prescribe particular products which are of more economic benefit to him.

## 2. POLICIES BEARING ON SUPPLY

The insurance organization tries to keep drug costs down by obtaining the product at the best price from producers and distributors. These measures can be grouped as follows: control of laboratory prices, restriction of promotion spending, control of distribution margins, and substitution policies.

### 2.1 Control of laboratory prices

This control may be direct, with prices set by the administration, or indirect, with control by the administration of the companies' profits.

Direct control of retail sale prices: this system consists in the administration setting maximum prices, by taking the calculated costs of the product and adding a certain margin for profits. It is known as cost pricing and the most well-known example of the system is the Italian case, although it is also practised in France, Belgium, Spain and many other countries.

In the case of Italy, calculation of unit costs is made using a series of mathematical equations which give a polynomial linear function whereby the price depends on the cost of raw materials, the cost of processing and packaging materials, and manufacturing time, multiplied by certain constant factors which are determined by means of costs surveys of a broad sample of laboratories. To these costs a maximum profit margin of 15% is added.

The structure of the Italian cost pricing system allows a fair measure of flexibility for the alignment of prices with costs. In other countries (e.g. Spain) there is not this flexibility and the high costs may make the product unprofitable.

This procedure is a powerful tool for controlling drug spending, when combined with a proper policy of price reassessment. It has the disadvantage of precluding the application of any selective policy of support for certain activities, or for laboratories engaged in research, etc. It generally encounters stiff resistance from the laboratories, which prefer liberalized price formation systems.

Control of company profits: This system is used in the United Kingdom and is known as the PPRS (Pharmaceutical Price Regulation Scheme). Pharmaceutical companies must submit annual accounts with an analysis of their profits. If profits are too high, the laboratory must pay a certain amount to the State and must lower its prices. Conversely, if profits fall, it may raise its prices.

Admissible levels of profit vary depending on the type of enterprise, number of people employed, investment, exports, research, etc., and range from 18%-20% for firms which innovate to 7% for those engaged in purely commercial activities.

This procedure achieves a satisfactory level of control over the industry and encourages future lines of development, although it is strongly challenged by the companies and requires the submission and analysis of a considerable volume of accounts.

### 2.2 Ban or restrictions on promotion

This entails limiting or prohibiting promotion and advertising activities designed to create a demand which is financed by the insurance organizations, which also pay the promotion costs included in the prices. For this reason, limits are placed on these activities (radio and television advertising, activities of travelling medical salesmen, free samples, etc.) in almost all countries.

Restriction may consist in allowing a maximum percentage on the volume of sales and applying some kind of sanction to companies which fail to comply with it. In the United Kingdom,[11] these costs are limited to 10% of sales, a figure it is hoped to reduce in subsequent years, although higher figures are allowed for smaller firms.

## 2.3 Control of wholesale and/or retail distribution mark-up

One way of reducing the total cost is to reduce the profit margins of distributors, i.e. wholesale stockists and pharmacies. These systems are usually differentially structured in order to compensate pharmacies in rural or deprived areas. These measures generally arouse opposition among the distributors.

## 2.4 Substitution policies

A supply-related measure which encourages price competition on the pharmaceutical market is the substitution of drugs prescribed by the doctor by specialties with similar characteristics and a lower price. Substitution of this kind may be undertaken generally for all products (including procurement by hospitals), or, as proposed by the Swedish Board of Health,[12] only for those which make the greatest impact on drug spending.

An interesting programme is the American "maximum allowable cost" (MAC), which consists in limiting payment for prescribed drugs to the cost of the least expensive existing equivalent, unless any differences in therapeutic effect can be demonstrated.[13] This measure is applied to welfare programmes.

## PHARMACEUTICAL DEMAND BY THE SPANISH SOCIAL SECURITY SYSTEM, WITH SPECIAL REFERENCE TO PRESCRIPTION CHARGES

The evolution in social security pharmaceutical spending in Spain, in pesetas at 1976 constant value, follows the pattern reflected in figure 1, which shows prescription spending at retail sale prices. During this period, which is characterized by a sharp increase up to a peak in 1976, two types of measures to control consumption were used: the pharmacopoeia up to 1967, and from then on, prescription charges of varying levels.

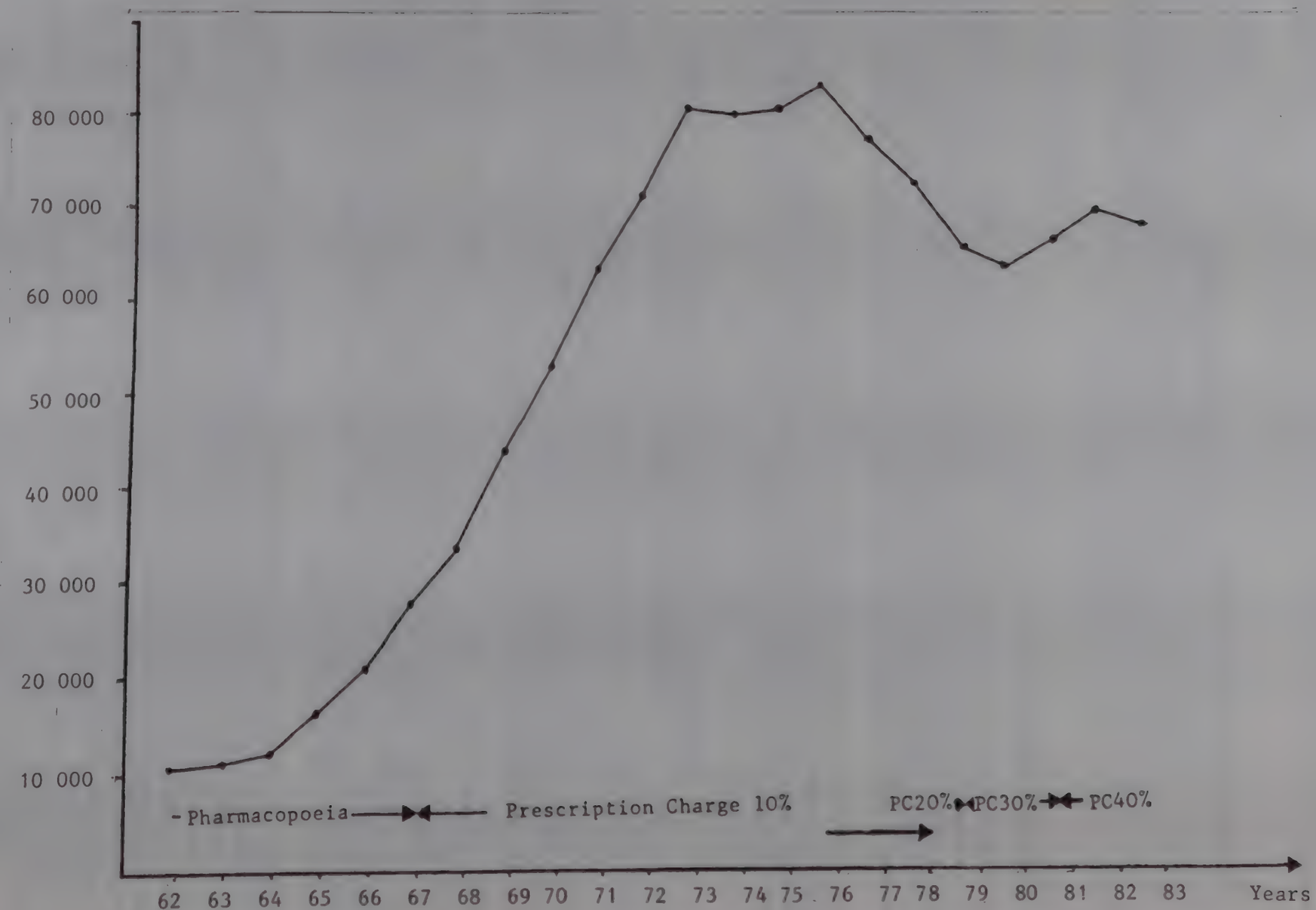
When sickness insurance was instituted in 1942, it was established that pharmaceutical coverage would consist of the items included in a pharmacopoeia which was to be periodically revised, under the control of the administering body (INP). The INP invited submission of tenders on a number of occasions, in order to select the specialities to be included both in the pharmacopoeia (list of active principles with their pharmaceutical formulae, concentrations and quantities) and in the catalogue (list of specialties meeting the requirements of the pharmacopoeia).

The Basic Law on Social Security of 1963, in base VI, authorizes direct procurement from centres of production and also lays down the obligation to determine by agreement the economic conditions to govern relations between the laboratories and the social security. In 1966, the Department of Health attempted an experiment in price control which was designed to remedy the excessive number of specialties and the price differences between comparable products, and to encourage specialization by the laboratories. The results were very negative,[14] for in the period from 1965 to 1968, the average drug price rose by 66.2%, while the overall increase in spending was 123.1%. This very marked rise was mainly due to the higher prices of widely sold specialties, while there was no fall in the price of those less widely consumed, and to the discontinued manufacture of smaller packages and the proliferation of larger packages.

The Decree of 23.12.1966 develops the principle of participation by the beneficiaries in the cost of drug provision in order to avoid "inappropriate, excessive or abusive" use of drugs, and this text simultaneously abolishes the pharmacopoeia and the catalogue. The contribution of the insured is determined as follows:

Figure 1

Expenditure on prescriptions at retail sale price (1976 pesetas)



(a) For drugs costing less than 30 pesetas, contribution of 5 pesetas.

(b) For drugs costing 30 pesetas or more, the 5 peseta contribution is increased by 1 peseta for every additional 10 pesetas, while the total contribution may not exceed 50 pesetas.

(c) Drugs supplied in social security establishments are excluded.

The immediate effects of the contribution of the insured on the cost of drug provision are very difficult to determine.[15] In the first place, owing to the difficulty of obtaining reliable statistical information for years preceding 1967.[16] Secondly, free dispensing was adopted in the same year as the prescription charge, and these two measures, although contradictory, impinge jointly on the economic results, which show a considerable increase in expenditure per insured patient (38% increase). The conclusion which may be drawn is that the prescription charge is less effective than the lists in keeping down consumption.

Structure of the charge, comprising a fixed amount plus a variable with a ceiling, meant that, as can be seen in table 1, its financial importance would decrease. From 1973 on, this decrease was accentuated by the exemption of pensioners from payment of the charge. The decrease in the participation of the insured in real terms in drug provision continued until a low was reached in 1977, when it was 8.5% of the total cost.

In 1978, there was an increase in the prescription charge and a change in its composition, forming part of a series of measures directed at curbing social security costs and raising fresh resources. From 1978, the charge was raised to 20% of the retail sale price and in January 1979 it went up to 30%. A further rise to 40% took place in September 1980. There were two exemptions from these increases: pensioners continued to be exempted, and certain drugs indicated for chronic disorders retained the 10% charge.

In the data in table 1, we can see the financial effect of the measures. In 1978, the increased charge raised the level of financing to 10.7%, which rose to 17.1% with the 1979 increase (30%), and in 1981, with the 40% charge, 19.4% of drug provision costs were financed. This figure has since fallen to 16.7% in 1983, although the percentage contribution has remained unchanged and without any ceiling. This phenomenon is the result of greater proportionate consumption by pensioners exempted from the payment of the charge.

The argument to justify successive increases in the contribution of the insured has been the curbing of unnecessary over-consumption. This ignores the underlying purchasing pattern of drug consumption: it is the doctor who prescribes and the consumer (patient) will obtain the prescribed product and pay the charge. If the charge is a factor reducing consumption, medically essential prescriptions will remain unused for economic reasons. If the charge does not reduce consumption, it will be solely a financial component. Exceptionally, there may be cases where the doctor is sensitive to the patient's economic situation and prescribes cheaper drugs, but if that is so, should he not also be aware of the difficulties of the social security? There is no doubt that a reduction of consumption is undesirable, provided that prescribing is appropriate, and if prescribing is not appropriate, action should be directed towards the relevant factor (doctors).

In Spain, a number of campaigns have been conducted since 1979, making use of the computerized processing of prescriptions, to inform prescribers of their level of prescription and the cost, concentrating particularly on prescribers incurring the greatest costs.[17]

We shall now attempt to analyse the effect these measures have had on social security prescription spending (excluding magistral formulae) from 1967, the date from which adequate information is available. In table 1, the evolution of prescription costs can be seen, peaking in 1976 and subsequently decreasing. It is important to note that the number of packages prescribed per person covered, expressed in units of individual consumption, grew from 12.5 units in 1967 to 17.0 in 1977, and then fell to 15.4 units in 1983.

Table 1

Social Security Expenditure on Pharmaceuticals
(in pesetas at 1976 constant value)

| Year | Prescription costs (specialities at retail prices) 1976 pesetas (millions) | % contribution by the insured | Units (No. of packages) of annual individual consumption | Average price per package 1976 pesetas | Available per capita income 1976 pesetas | Population covered by Social Security (thousands) |
|---|---|---|---|---|---|---|
| 1967 | 27 523 | 15.70 | 12.584 | 150.20 | 55 404 | 14 675 |
| 1968 | 33 321 | 15.42 | 13.548 | 165.60 | 58 598 | 14 967 |
| 1969 | 44 386 | 14.31 | 14.846 | 188.80 | 62 065 | 15 938 |
| 1970 | 52 507 | 13.13 | 13.688 | 211.20 | 64 859 | 18 264 |
| 1971 | 63 069 | 12.01 | 14.463 | 218.80 | 68 034 | 20 062 |
| 1972 | 70 093 | 11.32 | 14.734 | 226.20 | 73 455 | 21 176 |
| 1973 | 80 157 | 10.10 | 15.485 | 225.60 | 79 162 | 23 160 |
| 1974 | 79 154 | 9.48 | 15.757 | 204.90 | 83 501 | 23 891 |
| 1975 | 79 611 | 9.15 | 16.947 | 190.20 | 83 507 | 24 158 |
| 1976 | 82 109 | 9.10 | 16.977 | 175.20 | 85 236 | 26 793 |
| 1977 | 75 086 | 8.58 | 17.041 | 148.80 | 86 001 | 28 254 |
| 1978 | 70 201 | 10.70 | 16.691 | 135.80 | 87 450 | 29 461 |
| 1979 | 63 380 | 17.13 | 15.849 | 129.80 | 87 551 | 30 359 |
| 1980 | 61 143 | 17.82 | 15.577 | 125.70 | 86 945 | 31 107 |
| 1981 | 63 777 | 19.47 | 15.682 | 128.50 | 84 160 | 31 647 |
| 1982 | 66.201 | 17.72 | 15.237 | 134.90 | 83 963 | 32 170 |
| 1983 | 64 625 | 16.79 | 15.485 | 134.00 | 85 282 | 32 921 |

Sources: Ministry of Health, Pharmaceutical Payments Service
Bank of Spain: National Accounts

The series for the average price per package in pesetas at constant value rises from 150 pesetas in 1967 to 226 pesetas in 1972, then falls to 125 pesetas in 1980 and later rises again to 134 in 1983. The behaviour of the average prices must be connected with the policy of price increases authorized by the social security. After 1967, no revision of prices was authorized until 1975 (2.8%) and subsequently 1977 (5%), 1979 (6.7%), 1980 (11%), 1981 (9%), and 1983 (8%). The increase in the average price per package arose out of changes in prescription, either as a result of publicity and promotion directed at doctors, or through the substitution of old specialties by new ones.[18]

Total expenditure on prescriptions will depend on the following factors:

- average price per package prescribed, which, as we have indicated, depends on the policy of price-setting, and the marketing of the products of the laboratories;

- the population covered by social security, which has grown rapidly during the period analysed;

- the number of packages consumed per person insured, a variable which will reflect the morbidity of the population and also its tendency towards the consumption of pharmaceuticals.

These three factors form a whole, in which the effects of the prices, population and prescription-consumption habits on the social security can be distinguished. Total expenditure on prescriptions in fact amounts to:

Expenditure = (units/population) x population x average price per unit.

The policy of cost containment may be brought to bear upon any of these variables, although it is difficult to reduce the population covered and the trend is in fact towards the incorporation of further groups.

The average price per package depends on the price-setting policy approved by the health authorities, together with the process of product substitution and influence on prescribing habits practised by the laboratories.

For the number of units per person, the descriptive variables involved need to be determined. Taking a linear model with the variables of available income, prescription charge, a fictitious variable to cover information policy (value 0 until 1978 and 1 as from 1979) and the average price per unit, the following equation is obtained:

$$\underset{}{\text{UNIT/PERSON}} = 9.5112 + \underset{(0.0000107)}{0.000095} \cdot \text{INDIVIDUAL INCOME} - \underset{(0.033)}{0.11669}\ \text{PRESCRIPTION CHARGE}$$

The model has a multiple correlation coefficient of 0.874 and is 99.9% significant.

The number of units consumed rises with the income available per person and decreases on average by 0.11 units for each percentage point of increase in the prescription charge. The number of units is not affected by the average price of the products, nor, apparently, by the information policy followed.

Estimating the model in logarithmic form, in order to obtain a multiplicative structure with calculation of the elasticity of the descriptive variables, a value of $R^2 = 0.89$ is obtained and is 99.9% significant:

$$\text{UNIT/PERSON} = 0.31832\ \text{INDIVIDUAL INCOME}^{\underset{(0.0644)}{0.4049}}\ \text{PRESCRIPTION CHARGE}^{\underset{(0.0415)}{-0.1321}}$$

where sales elasticity is 0.4 and prescription charge elasticity is -0.13. This means that a given percentage increase in the prescrition charge gives rise to a decrease of 0.13 times that percentage in the number of units consumed.

Annex 3.3



Looking at the overall expenditure on prescription of specialties at retail prices, descriptive models with linear and logarithmic structure can be established. The linear model is :

$$\underset{}{\text{EXPENDITURE}} = -52.213.8 + \underset{(22.15)}{222.3}\ \text{PRICE} + \underset{(0.256)}{0.874}\ \text{INCOME} - \underset{(322.1)}{1169.19}\ \text{PR.CHARGE} + \underset{(0.481)}{1.0439}\ \text{POPULATIO}$$

with a correlation coefficient of 0.984, and 99.9% significant as a whole and in all its variables. Interpretation of the coefficients shows that an increase in the contribution o the insured of one percentage point in the prescription charge reduces spending by 1,169 million, whereas 1 peseta off the average price means a saving of 222 million. As the standardized coefficients show, the model indicates that costs are most sensitive to variations in income, then to price and population, and in the last place to the prescription charge. The logarithmic form of the model is as follows:

$$\text{EXPENDITURE} = 0.000034343\ \text{PRICE}^{\underset{(0.066)}{0.820}}\ \text{POPULATION}^{\underset{(0.188)}{0.672}}\ \text{INCOME}^{\underset{(0.328)}{0.953}}\ \text{PR.CHARGE}^{\underset{(0.060)}{-0.154}}$$

where $R^2 = 0.99$, and is significant both as a whole and for each term considered separately. The indices are the elasticity of the respective variables, and as we have already pointed out, the variable with the greatest elasticity is income (0.95), followed b price (0.82), population (0.67) and prescription charge (- 0.15). But, if the containment of pharmaceutical spending is sought, the most effective variable to act on would be the price, since the possibility of influencing population and income can be set aside, and the prescription charge is the variable which has the least effect on spending.

In any case, the models for spending and units/population shows that the prescription charge does restrain consumption, both in volume and in total monetary value. In our view, this is a "perverse" or undesired effect, insofar as it indicates that patients are doing without some of the drugs prescribed by the doctor, or that the latter has placed the patient's economic situation above therapeutic considerations when making his prescription.

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ANNEX 3.4

DAP/WP/PF/84.4*

WORLD HEALTH ORGANIZATION

ORGANISATION MONDIALE DE LA SANTE

ENGLISH ONLY

Working paper for

MEETING ON DRUG POLICIES AND MANAGEMENT:
PROCUREMENT AND FINANCING OF ESSENTIAL DRUGS
Madrid, 22-26 October 1984

# PRICE DETERMINATION OF PHARMACEUTICAL PRODUCTS AND OUTLINE OF PROCUREMENT STRATEGIES FOR ESSENTIAL DRUGS

by

Bent Husby and Ernst Becher
WHO Consultants

CONTENTS

| | | Page |
|---|---|---|
| 1. | Introduction and Summary | 2 |
| Part I - Market Structure and Price Strategy in the Pharmaceutical Industry | | |
| 2. | Scope of Analysis | 2 |
| 3. | The Pharmaceutical Industry | 3 |
| 4. | Economic Characteristics of Pharmaceutical Production | 5 |
| 5. | Research and Development | 6 |
| 6. | Pricing to Obtain a Contribution | 7 |
| 7. | The Market Fabric | 10 |
| 8. | International Price Comparisons | 13 |
| 9. | Price Discrimination | 15 |
| Part II - Outline of Procurement Strategies for Essential Drugs | | |
| 10. | Current Status | 16 |
| 11. | WHO as a Broker | 18 |
| 12. | Limited Participation and Assortment | 19 |
| 13. | Negotiating Package Deals | 19 |
| 14. | Ultimately a Commercial Basis | 20 |
| 15. | A Fund for International Drug Procurement | 20 |
| 16. | What Next? - A List of Questions | 22 |
| Annex: Explanatory Notes and List of References | | 25 |

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* This paper is the updated and expanded version of Price Determination of Pharmaceutical Products, a review and an outline for a strategy for obtaining lower prices for essential drugs, prepared by Bent Husby for the WHO Regional Office for Europe as document EUR/PDU/82.1 in July 1982.

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## 1. Introduction and summary

It has been estimated that in many developing countries 60-70 percent of the population do not have constant access to even the most essential drugs, and yet, a very large proportion of the health care budget in these countries is spent on pharmaceutical products. The need for a strategy to obtain essential drugs for these underserved populations at the most favourable terms is obvious. One step towards development of such a strategy is an understanding of the price mechanisms for the pharmaceutical products.

Medicine prices are controversial - in the developing world and the developed world alike. Political and popular demand calls for reasonable prices in this area - almost above all other areas. The difficulty is to give a practical meaning to the term "reasonable". This report tries to explain why.

Central elements in the price controversy are:

(a) price differences from one country to another - or even within countries - of seemingly identical products;

(b) the fact that direct factory costs appear to be almost irrelevent to manufacturers selling prices;

(c) disagreement with industry on the nature and extent of its marketing efforts.

To get behind the catchwords implies an understanding of the basic economic structures and conditions, hence Part I of the report discusses the characteristics of the pharmaceutical industry, its performances, production, research, development - and pricing. Prices are determined by market conditions - not by full cost product calculations. Price control and other statutory means may quite clearly exert influence - with desirable and less desirable effects - but they will hardly change the basic principles. A further analysis of the market fabric and problems of price comparisons and the policy of price discrimination is thus in order.

In Part II, the report outlines possible strategies for procurement of, and obtaining lower prices for, essential drugs in the developing world. There is quite obviously a case for new approaches and mechanisms, and further - since prices in general are determined most of all by competition - the logical step is to enhance that competition.

# Part I
# Market Structure and Price Strategy in the Pharmaceutical Industry

## 2. Scope of Analysis

This report is written for internal WHO purposes with a view to the problems of the Action Programme on Essential Drugs; it attempts - within its limitations - to come to grips with the principal problems of the price determination of pharmaceutical products at the manufacturer's level. Pricing of wholesaler or retail trade has not been dealt with.

Annex 3.4



Not only are prices for pharmaceutical products a politically sensitive subject, also an assessement of price determination is bound to be controversial - especially if it is a short one. Limited size means selection from a very large and complicated subject. Selection may imply subjectivity. In this case observations, analyses, and views have been drawn from independent analysts[1] writing official reports for the purpose of providing the background material for a possible special price control legislation or other statutory regulations for the pharmaceutical industry. Even so, some may disagree - especially with the selections. They are made deliberately, however, not for the purpose of argument or propaganda, but because they are believed to be relevant for the discussions and negotiations of the strategy.

The report deals with a number of important - but also quite elementary - elements in price determination and micro-economics of the pharmaceutical industry, especially as seen in the developed world. No specific analysis of price determination in the developing world has been attempted. Nor have more specialized elements been analysed. One such significant element is transfer pricing, i.e. the determination of prices which a subsidiary company in one country pays to its parent company in another country for supplies of raw materials or semi-manufactured products. For the immediate purpose of the report, this need not be a defect.

## 3. The Pharmaceutical Industry

Drugs and medicines cover a wide field, from the tinctures of the nature healer to the sophisticated synthetized pharmaceutical specialities. This report is about the products of the pharmaceutical industry and in particular about pharmaceutical specialities.

### 3.1 Young, dynamic, international

Several companies in the industry have roots quite far back, mostly in other branches of chemistry but modern pharmaceutical industry is young; it has evolved after the second world war; it is very dynamic and it is very international. The future of the individual companies rests on their ability to develop new products, new or improved therapies. Research, development and exchange of information are very essential and competition is fierce. Patents and trade marks are important but development is quick, often too quick to obtain the full benefits of the temporary monopoly a patent should provide.

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1 See Annex: Explanatory Notes and List of References:

The Danish report (reference no. 1) was written by civil servants of the Monopolies Control Authority, assisted by experts from the staff of the Ministry of the Interior and the National Board of Health, Copenhagen.

The Swedish report (reference no. 2) was written by a highly esteemed university professor (retired) and specialist in micro-economics. Until the time the Swedish Government asked him to write his one-man white paper on pharmaceutical pricing, Professor Sune Carlson had no special knowledge of - or connexion with - the pharmaceutical industry.

## 3.2 Concentration

Even in the global perspective, this high technology industry is also a relatively concentrated industry. Globally, there are more than 10 000 companies that could be called pharmaceutical manufacturers. Of this number, however, no more than about 100 companies are significant in terms of international market participation. These 100 firms supply about 90% of total world shipments of pharmaceuticals, the latter estimated currently to be worth US$ 100 billion at manufacturer's prices. The top fifty drug companies in the developed market economies account for nearly two-thirds of this total while the leading 25 companies account for about half[1].

The pharmaceutical market is in no way a homogenous one. It is subdivided in smaller ones. In the submarket for the treatment of diabetes there are several types of insulin and oral drugs of different modes of action. They compete with one another - but not with penicillin. All of the internationally dominant companies are active in several sub-markets, but hardly any of them in all the sub-markets.

## 3.3 Hardware and software

There are two principal elements in the performance of the pharmaceutical industry. They may well be termed a Hardware and a Software performance. The industry supplies products and knowledge about the products. This, in principle, is not very different from the performance of many other research or technology intensive industries producing capital goods or producers articles[2].

As opposed to other industries - such as the electronic data processing industry - the pharmaceutical industry receives no payment for the supply of its software - but only through sales of its hardware, the pharmaceutical specialities or raw materials. In the course of time - and especially for "me-too" products and synonyms - the software gradually becomes less important.[3]

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1 UNCTNC (5), page 22 and more recent information

2 To illustrate the central problems of the pharmaceutical industry, its performances and pricing, Carlson (2) points to a number of analogies, the relevance of which may in itself be controversial. An example, page 8:

"The manufacturer of ballbearings develops a new kind of speciality bearings. He provides the manufacturer of machines not just with ballbearings. He also puts all his application and usage know-how at his disposal; he helps him to solve certain problems of friction. Often the extent and realibility of this help means more in the choice of supplier than the price itself. The costs of some ballbearings carry little weight in the total costs of the machine but if the bearings do not function as intended, the machine will be worth only little."

3 Carlson (2), page 10

Annex 3.4



The pharmaceutical industry is frequently criticized for spending excessively on sales promotion. The difficulty is that while technical service in many high technology industries is separated from the direct sales activity, the opposite is the case in the pharmaceutical industry. Normally, both activities are in the hands of the same people. How the staff costs should be distributed between software and sales efforts is difficult to say. Industry holds that practically all costs refer to medical information. The critics claim that most is commercial promotion.

### 3.4 Breakthrough or "me-too"

There are important distinctions in the performance of the industry and of the individual companies. Most spectacular, of course, is the development and marketing of totally new preparations which constitute a breakthough in therapy; less spectacular are introductions of "me-too" preparations through which competing companies seek to obtain shares of the markets. These later entries may represent small, but not insignificant, steps forward in therapy. However, both slightly different "me-toos" and the obviously synonymous products which often appear when the patent protection has ceased to function may be important price competition elements.

Obviously, cost structure in a research based and highly innovative company is quite different from a company which establishes its business on the exploitation of the research and development results of others.

## 4. Economic Characteristics of Pharmaceutical Production

For an understanding of pharmaceutical pricing, two elements of the micro-economics of the pharmaceutical industry are important.

(1) The variable (or direct) costs are low relative to the manufacturer's price. The variable (or direct) costs are those costs which will not be incurred if the production of the product - or batch - in question is not made, that is, raw materials, packaging materials, batch tests, energy, labour, etc.

(2) In a company producing several different products and using the same or partially the same production capacity for their production - and the same overhead structure for their subsequent marketing, distribution, etc. - there is no logical way of distributing the fixed costs on individual products or over time - from one year to the next[1].

The principal groups of costs to the pharmaceutical manufacturer are:

- research and development,
- information and contacts,
- distribution,
- administration,
- production capacity.

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1 Carlson (2), page 6

The largest part of these costs are fixed costs. They will have to be covered by contributions from sales revenue.

In order to determine the cost structure of pharmaceutical specialities, the Danish Monopolies Control Authority in 1977 conducted an analysis of all such products with a turnover in Denmark in 1975 of over Kroner 1 million at the manufacturer's level. In the analysis it was established [1] that average variable (or direct) costs amounted to 25 percent of the manufacturer's price. There is considerable variation in the material - from 10 to 50 percent - but the average of 25 percent corresponds well to indications from other supplier countries.

The Danish manufacturers were asked to describe their calculations and price determination methods. Most companies do calculate variable (or direct) costs of manufacture for individual products. Beyond that, little or no effort at all is made to distribute costs on individual products or groups of products - and not for the purpose of price determination.

This means that the notion of "cost price" meaning full cost of production for an individual product - under which the manufacturer cannot sell without actually incurring losses - is really an abstraction of very little practical use.

## 5. Research and Development

### 5.1 Investment in knowledge

To the research-based companies, investments in research and development mean investments in knowledge and contacts that may well annually amount to more than twice the investments in tangible assets. To invest in research and development may be described simply as a maintenance for a period of time of a research and development capacity, that is, salaries for a highly qualified staff often of very different professional specialities, adequate support staff, contacts for exchange of information and clinical trials, laboratory equipment, test materials, etc., etc.

### 5.2 Magnitude and purpose

The level of expenditure for research and development is a distinguishing feature for the pharmaceutical industry as compared to most other manufacturing industries. An investment of 10 percent of annual sales revenue would be a typical figure for a research based pharmaceutical company. In Denmark this is 10 times the average for all manufacturing industries.

Again, the very notion of research in the pharmaceutical industry is subject to controversy. What research, and for what purposes? Only little of the research here is basic research, and some of the costs refer to laboratory activities in the outskirts of the general concept of scientific research. The bulk is applied research, and of that a good part for the purposes of

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1 Monopoltilsynet (1), page 249

undermined. In his assessment of his product's value to potential customers and the probable behaviour of competitors, the manufacturer will generally determine the price in relation to the alternatives already on the market.

But in cases where the product is unique, the pricing decision becomes more subtle. Here it involves a highly subjective judgement of what price will yield the greatest profit. The first manufacturer in the market may choose "penetration" pricing, i.e. to sell as cheaply as he can afford to based on a reasonable estimate of production volume, or alternatively, he may choose "skimming" pricing by charging very considerably more[1].

As an example of "skimming pricing" followed by considerable price reductions under the pressure of competition, the price development for broad spectrum antibiotics in the USA is mentioned. The price of chlortetracycline fell in the time from 1948 to 1974 from approximately US$15 to approximately US$3 for 16 capsules of 250 milligram. At the same time the price of the least expensive analogous product, tetracycline, fell to approximately US$1.

Conversely, the price policy for the tranquillizers Librium and Valium is mentioned as an example of "penetration pricing." While the broad spectrum antibiotics had to come down from US$15 to about US$5 in order to gain general acceptability and to discourage further market entrance, Librium and valium were introduced at prices which were readily seen by doctors to represent good value in terms of patient benefits. The products were a monumental success and prices were maintained unchanged for a very long time.

Admittedly, however, the proponents of these views have not been in a position to document - on the basis of calculations from manufacturing costs - to what extent these prices represent levels below which the manufacturer cannot "afford" to sell.

## 6.5 Costs recouped - lower prices?

It has been argued - indeed even enacted - that while the companies should be permitted to recover their research and development expenditure from current sales, they should on the other hand be obliged to lower prices once the costs were recovered - for instance, after a period of 8 years after the introduction.

This argument very clearly collides with the fact that the costs of development of the individual product cannot be determined - at least not with any reasonable degree of accuracy. The argument is thus economically meaningless - the more so as many research projects fail; they do not lead to the marketing of products through which it would be possible to recoup the investment. The research which led to the products sold today will often have taken place far back in time. The research taking place today and which is financed by the sales of today will - hopefully - lead to progress in the therapy of tomorrow.

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1 Teeling-Smith (4), page 9

### 6.6 Conclusion

The Danish study concludes: Profits derived from different products in the analysis vary considerably. Some products contribute only little towards fixed costs of research investment and net profit. Among the products that contribute the most are many that have been on the market for a considerable number of years[1].

## 7. The Market Fabric

If price determination for pharmaceutical products depends so much more on market condition than on manufacturing costs, then what are these conditions? The obviously competitive situation between two close substitutes has already been mentioned - but to the manager of the pharmaceutical company, there is a multitude of factors which influence conditions of operations and factors to consider in connection with his price decisions.

### 7.1 Financial and technical requirements

A number of conditions under which the pharmaceutical industry must operate quite clearly favour large and financially strong companies.

Not only must the final product be submitted to the most rigorous scrutiny before marketing approval by the health authorities can be obtained, also the manufacturing installations and the qualifications of the personnel in charge must meet exacting standards. Demands of financial strengths are obvious in connection with the very considerable investments in research and development which are necessary to produce new products and which contain important elements of the risk of failure. In addition, considerable time - maybe years - will pass before marketing approvals are obtained and sales revenue finally comes in.

The research results in the chemical industry may sometimes be utilized in the development of pharmaceutical products - and vice versa. Also methods of production may be related. This together with factors mentioned above explains the development of pharmaceutical industries as offsprings of larger chemcical industries. Even goodwill may be transferred from the one area of the concern to another.

The aggregate financial and technical requirements act to potential newcomers in the industry as formidable barriers against entry and explains in part the globally concentrated nature of the industry.

### 7.2 Market size

Even in the European Communities, where one of the central principles is a common market with free movement of goods between the member countries, there is no common market for drugs. Each country is a market to itself. In spite of years of efforts at harmonization of rules of registration and possibly mutual recognition of marketing licences, it is still the sovereign decision of each country if it will admit a pharmaceutical product to its market or not. And notably different decisions are reached in the neighbouring countries not otherwise very different from one another.

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1 Monopoltilsynet (1), page 146

Price, market size, and market share are the basic parameters for sales revenue, the economic framework within which the company must operate in that market. The demographic facts of the market are readily established. But both per capita spending of pharmaceutical products and the market share of different groups of products vary from market to market. A study[1] of five EEC countries showed threefold variation in per capita spending whilst the total market size varied sixfold. Antibiotics formed only 4 percent of the market in Germany but 18 percent in Belgium. Psychotropic drugs were 8 percent of the UK market but only 2 percent of the Italian market. Whereas cardiovascular drugs were 8 percent of the Italian market they were 18 percent of the German market.

## 7.3 Nature of competition

Of primary importance are the number of substitutes, their age and immediate outlook for new entries in the market. The position of the different competiting products is influenced by the degree of patent protection. Often patents are taken out at an early stage of development; patents are granted from the time of application; thus considerable time - maybe more than half of the normal time of protection of 15 to 20 years - is used up while development is finished and marketing approval obtained.

Patent protection is of varying strength. Some countries admit patents of an active substance itself, others only patents covering the manufacturing processes which lead to the substance. The latter constitutes a weaker protection and a lower barrier of entry for potential competitors. Over and above patent protection, companies may choose to retain part of their technical advantage in the form of scientific and manufacturing know-how simply as business secrets. Patents do offer protection for a limited time - but on the condition of full publication of details of the protected products or processes.

As opposed to patents, trademarks may be obtained for an indefinite period of time. In connection with the introduction of a breakthrough product supported by ample information on characteristics and therapeutic possibilities of the product, the trademark can be very instrumental in preserving goodwill for that product even after expiry of patent protection and after the introduction of less expensive substitutes or synonyms.

Whether the brand loyalty is strong enough to secure the market share of the original product depends to a large extent on the price policy in combination with the promotional efforts of the competitors. Not only the quality of the information on the competing product, but also advertising of more commercial nature may be significant. Advertising the product as the result of a national industry rather than imports may be effective.

While the individual countries through their prerogative of issuing or refusing marketing licences, their demands in respect of packaging material, etc. do create isolated markets with each of their individual characteristics, there are a few exceptions. Some countries do permit - to some limited extent - parallel imports where import to a high price market are made from a

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1 Cooper (3)

low price country. The parallel importer typically buys from a wholesaler in the low price country and sell to wholesalers in the high price country (or to his retail customers if he himself is a wholesaler). The transactions are outside the control of the manufacturer and his representatives and may impose very uncomfortable competition. It is the manufacturer's own product against himself if his different price policies offer adequate differentials.

## 7.4 Price control

A factor of clearly crucial importance in the price decisions are the conditions imposed by a possible price control. A frequent stipulation in legislations on drugs is a requirement that "prices of pharmaceutical products must be reasonable". The difficulty is to determine the meaning of the word "reasonable". Price control systems may be organized in a variety of ways. It may be special to pharmaceutical products or it may be a general control which applies to all commodities; it may be permanent or occasional; it may be more or less rigorous. Very commonly the difficult assessment of the "reasonableness" is made through price comparisons either nationally with similar products and in some cases in combination with an assessment of therapeutic value, or internationally for the particular product in question. Here the price in the home market may be of special significance.

Price control mostly deals with all levels of distribution, but the real difficulties are in establishing a criterion for the price determination/ control at the manufacturer's level. Some countries do base their control system on individual product calculations of manufacturing costs[1]. And yet another system is based on company profits rather than product prices.

The downward pressure on prices through price control - or price stop policies - often relates to the supply situation in the market. Countries with their own research based industries would exert less pressure than others primarily dependent on imports.

## 7.5 Characteristics of demand

Different markets have different regulations in respect of prescription requirements, but a very large proportion of the market is subject to the decisions - purchase decisions really - of physicians. In view of the fact that real costs to the consumer may be reduced by public or private reimbursement, the first consideration of the physician most likely will be

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1 Carlson (2), page 40: "as I have pointed out, I consider it practically impossible through cost analysis to determine what is a reasonable price for a given pharmaceutical product. When some countries do so anyway, it could indicate that the authorities there see this differently. But I don't think so. The product calculations should rather be seen as a pretext when one wishes to press prices down or something that one resorts to because of unwillingness to work without the support of detailed rules. One does not want to negotiate or argue. How difficult it is for a person in authority to do without objective norms is known to anyone who has tried to split a soft drink between pre-school children without the use of identical glasses that may be filled to exactly the same level."

the choice of the therapeutically most suitable product for his patient. If economic considerations do enter into the process of decision, most likely the physician will think of his patient rather than the public purse or an insurance company. In the - not particularly frequent - situations, however, where doctors themselves dispense drugs to their patients, the whole economic outlook of the physician may be quite different.

In the institutional markets the choice by hospital committees may be quite decisive not only for the direct consumption in the hospital, but also through a carry-over effect in the primary health care sector adjacent to the hospital. On the national level governments may have different attitudes ranging from the use of monopsonistic powers to exert a downward pressure on prices to an attitude of free play of market forces.

In yet a different market - the market for veterinary pharmaceutical products - conditions are different. The owners of the animals pay themselves for the medication. The costs are mostly costs of production, they should be kept low; and anyway, the emotional elements in the decisions are not the same. As a result, profitability for the pharmaceutical companies in this market is lower.

### 7.6 The marketing decisions

It is on the background of this mesh of different parameters that the pharmaceutical manager must assess his own strategic position and make tactical marketing decisions.

How large a share of the market? How much sales volume? How much information needed? Compatability with present image and marketing capability? Promotional constraints in law or by agreement? Advertisements rather than representatives? Net contributions at different prices?

Price determination is one of the marketing decisions. But only one of them.

## 8. International Price Comparisions

International comparisons of prices for pharmaceutical products are made not just as a part of price control systems, but also for the more general purpose of studying the overall effect of price control, other policies, or simply the reasonableness or otherwise of pharmaceutical prices.

In view of the fact that pharmaceutical markets are so different, there is from the point of view of economics, no more logic to price equality than to price inequality[1]. And indeed, the methodological problems inherent in international price comparisions are very discouraging, and the scope for unintentional bias and ambiguity of findings is enormous.

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[1]Cooper (3), page 22

A definition of purpose is important. Where the problem is to compare costs to the end consumer, consideration must be given not just to manufacturer's price but also to trade margins in wholesale and retail levels, as well as to differences in reimbursement and possible sales taxes. For individual product comparisions, identity must be established both in regard to the manufacturing company as well as to the product, that is, active substance, other ingredients, quantity of substances, composition in general, strength, form of dispensing and pack size. Then differences in markets must be considered. Does the product have a comparable position in therapy? As indicated earlier, considerable differences do exist. In one country ampoules may be much more widely used and tablets in other countries. Differences of this nature are reflected in price levels. What influence do price control or other public policies exert in the respective markets?

Currency rates of exchange change frequently, and at times dramatically. Industry has pointed out repeatedly that at the marketing of a new product in several markets simultaneously, a uniform price level is attempted. In the course of only a few years, however, considerable differences result from changes in rates of exchange in combination with price controls and other markets' constraints which make adjustments difficult.

For more general comparisons aiming at the broader perspective of overall effects and general price levels, the additional problem arises of establishing a suitable assortment of products for the comparison. Because of the differences in therapy traditions, this problem becomes as much more aggravating as the number of markets in the comparison increases.

In a very general way - and without precision - price levels may be classified. Among European markets, the Netherlands, Switzerland and the Federal Republic of Germany may be found in a high price level bracket. Austria, the Scandinavian countries and the United Kingdom in a medium group with France, Italy, and Belgium in a low price group. But a study of European pharmaceutical prices lead to the following conclusion[1]:

"International comparisons of prices are at best extremely hazardous undertakings. Any results which emerge need heavy qualification and cautious interpretation. Small changes in methodology and in the sample size and composition can produce dramatic changes in the results. In no country are all prices consistently higher than in another. In this survey the overall results suggest that pharmaceutical prices in France are considerably lower at current exchange rates than those in Germany; lower than those in Switzerland and probably those in the United Kingdom. These conclusions however, are seriously dependent upon the survey making adequate allowances for varying market structures; the predominant form of product presentation; the typical pack size and the company and therapeutic make-up of the sample. Further, exchange rate movements and purchasing power disparities could go a long way towards accounting for the price variations."

"There is however nothing irrational or necessarily reprehensible about price variations, nor or they particular to pharmaceuticals. Much the same order of variation occurs for example with radios, washing-up liquid and bread. The EEC is in no sense a single unified market, prices vary due to differences in both cost and demand conditions. In the case of pharmaceuticals, the

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1 Cooper (3), page 23

markets are different in both size and structure. Many of the therapeutic differences are deep-seated and result from prescribing habits acquired in university medical schools where traditions and attitudes may be very different between nations. To change these established patterns is likely to be a very long term task ".

9. Price Discrimination

It may be difficult or impossible to establish whether price differences from country to country are the result of a deliberate price differentiation on the part of the manufacturer or result from other factors. As mentioned earlier, a price differentiation may be imposed in the form of price control or simply price stop measures by the authorities.

The fact remains, however, that in a number of situations it may be economically advantageous for a manufacturer to use price discrimination as part of his overall marketing policy.

The practice of charging different prices to different customers for the same product may spontaneously be regarded as unacceptable, but undoubtedly such pricing policies are far more prevalent in the general economy than normally recognized. It should suffice to mention a few examples. The price of alcohol depends very much on the intended use as a beverage or as a technical household article for cleaning purposes. The rate for telephone calls vary in time; business calls must be made during business hours; family calls can wait till later in the day when rates are lower. Children are admitted to entainment or public transport at lower prices than adults. The term "dumping" in connection with foreign trade is not at all unfamiliar, "reverse dumping" may be more so. But turning back to pharmaceuticals, one European price control system for drugs is quite plain in its pro-export attitude - low prices at home, high prices permissible abroad where possible.

Micro-economic theory on pricing points to three prerequisites for conducting price discrimination:

(a) it must be possible to separate markets;

(b) demand elasticity must be different in the different markets;

(c) the competitive situation in general must permit the seller to conduct price policy.

The need for market separation is not very difficult to see. Price discrimination is not viable if the result is that the products from the low price market flow - back maybe - into the high price market and cause a breakdown there. In the area of pharmaceutical products, market separation in respect of pharmaceutical specialities (packs for the end consumer) may be relatively easy to obtain. Labelling indicates which market is intended, and attempts to use it elsewhere may readily be foiled by legal marketing requirements. It depends of course on the depths of organization and law enforcement.

In the developed world, demand for pharmaceutical products as compared to other commodities may undoubtedly be considered quite inelastic. Social differences within these markets are compensated by public reimbursement or private insurance arrangements. In rural or marginal areas in the developing countries the situation is quite different. Any price - except may be the very lowest - may be prohibitive irrespective of needs and of the attractiveness of the product.

The theoretical requirement of a position to conduct price policy refers mostly to the competitive situation, that is, will the competition allow the manufacturer to maintain a high price in a market where demand elasticity would permit this as a worthwhile policy. To the manufacturer of pharmaceutical products two important factors further influence policy decisions on possible price discriminations; one "pro" the other "contra".

(1) The low variable (or direct) cost of manufacture (25 percent or may be even 10 percent of "normal" commercial prices) will make it attractive to obtain a supplementary business even if it can be obtained only at a reduced price provided a production capacity is available (that is, for which there is at the moment no better use). So long as the price still brings a contribution - the difference between variable costs and the price - the company will still be better off by accepting the low price business. In economics a modest but positive contribution is better than none at all.

(2) Price control authorities generally frown at price discrimination. What the manufacturer in the politically sensitive area of pharmaceuticals may well fear is the attitude: if you can sell this cheaply there, then why not as cheaply here?

From time to time complaints are made that pharmaceutical companies sell, or attempt to sell, inferior pharmaceutical products in the developing countries at low prices. It may have nothing to do with price discrimination but rather with the micro-economics of perishable products. Pharmaceutical products are perishable; they have limited shelf life; some must be kept in refrigerated storage.

When the owner of a perishable commodity faces difficulty with his product because of impending expiry or because it fails to meet quality standards, he stands to take a loss. Economic rationale urges him to minimize the loss by selling - quite independently of the cost of manufacture or purchase - at the best price the commodity will fetch. Any price is preferable to a total loss. Where standards of quality are the least exacting, the best possibilities may be found.

## Part II
## Outline of Procurement Strategies for Essential Drugs

### 10. The Current Status

In a progress report to the 37th World Health Assembly, the WHO Executive Board explains that the concept of essential drugs has been conceived and developed by WHO over the last five years. There are two major achievements:

Annex 3.4



- It has helped to create an awareness of the essential drugs problem in a number of countries, leading to the definition and start of implementation of national drug policies.

- It has contributed greatly towards creating international awareness of the possibility of harmonizing the interests of a majority of developing countries and the interests of major producers of drugs.[1]

Both Member States and industry have responded to the challenge of the Action Programme on Essential Drugs, and yet the early expectations have been only partly met.

The Executive Board points out that a system of international procurement developed by UNICEF has consistently been able to obtain good prices for a limited number of items and that in 1983 the system of international bidding for essential drugs to be supplied to the United Republic of Tanzania resulted in some of the lowest prices ever seen for essential drugs. Several prices were well below those quoted by UNIPAC, the UNICEF packing and assembly centre, Copenhagen. UNICEF, in collaboration with WHO, is planning to have its annual drug procurement with interested developing countries on one large annual international tender. International competitive bidding on vaccines has produced equally low prices for the most common vaccines. Moreover, WHO and UNICEF are collaborating to standardize labels, and an easily-identifiable logo for essential drugs is being tested in the field.

The Executive Board reports that the dialogue with the pharmaceutical industry continues. Contacts with companies which are not members of the associations belonging to the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) will be expanded to identify additional potential sources of drugs and technical assistance. The cooperation with IFPMA continues. For example, companies of the Federal Republic of Germany, Switzerland, and the United Kingdom have supplied anti-malaria drugs to WHO at low prices; and the tender for the United Republic of Tanzania attracted 62 bids--slightly more than half of the successful ones from IFPMA member companies.

At the 37th World Health Assembly, the Executive Vice President of IFPMA referred to both the tender for Tanzania and some subsequent tenders for Bangladesh and Haiti; and he underlined that the initial offer (from 1982) by some 60 IFPMA companies to supply about 250 products still stands.

He referred to five drug delivery projects which have been completed or which have been started or which are likely to start very shortly--in Gambia, in Sierra Leone, in Senegal, in Burundi, plus one scheme for which a number of substantial British companies had allocated a quarter of a million pounds for a pilot project to be established in a less developed country not yet named. The cost of the various activities is estimated by IFPMA to be of the order of several million US dollars.

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[1] WHO (6), page 4

Even so, the results are clearly not satisfactory. WHO states (in 1984) that the IFPMA offer made in 1982 to supply drugs and services at low prices has not yet been applied, while IFPMA in an informal discussion in October 1984 expressed surprise, the industry did not understand why the programme had not progressed further. IFPMA--that is, the companies, members of IFPMA associations--had been invited to participate or contribute to an action programme involving supplies of goods and services, mostly referred to as "package deals" involving supply of drugs at "non-commercial"--that is, very low--prices. In view of the possible difficulties with price control authorities elsewhere (as referred to in section 9 above), information about the non-commercial prices should, however, be kept confidential. What eventually did materialize was primarily the call for public tenders. This to the industry is quite different. Tender prices are public.

What is of paramount interest in this connection is that the industry spokesman thought that "non-commercial prices" might well be below tender prices--in spite of the fact that the tender prices in the case of the Tanzania tender 1983 resulted in some of the lowest prices ever seen for essential drugs.

## 11. WHO as a Broker

In connection with the Action Programme on Essential Drugs, WHO has depicted itself as an "honest broker"--a mediator between the pharmaceutical industry and the Member States. Negotiations were undertaken with the pharmaceutical industry as represented through the accredited NGO, IFPMA. These were negotiations of principles where, among other things, the industry representatives explained a number of factors which in connection with supplies at low, non-commercial prices would have to be taken into account to provide necessary safeguards for companies--and also insure success of the programme--but neither WHO nor IFPMA would wish to become directly involved in price negotiations.

Perhaps the task of the broker to bridge the gap of a complex arrangement between 60 companies and a number of sovereign states has been underestimated by both WHO and IFPMA. To IFPMA, and maybe especially to the 60 companies who pledged their support, the outcome of the negotiations now appear to be imprecise. A better understanding between prime supplier and end user would be desirable and--in the opinion of IFPMA--such an understanding should preferably be based on a public document on the various conditions to apply for deliveries under the action programme. WHO and IFPMA--in the context of the Action Programme on Essential Drugs, both brokers or mediators--seem at this point equally disappointed. The practical problem is clearly one of initiatives to ensure satisfactory dynamics and development. IFPMA would welcome a round-table meeting of participants--that is, representatives of the about 60 companies and representatives of the countries who take part in the Action Programme. If for practical reasons such a round-table meeting cannot be brought about within a relatively short time, WHO should consider other operational steps to ensure practical results from the positive industry attitude. This could be the deployment of staff members or consultants in numerous negotiations with the two parties or, more precisely, with the multiple entity of participating companies and country. First, however, a number of strategic decisions should be considered.

Annex 3.4



## 12. Limited Participation and Assortment

At this point, it would seem obvious to strive for country results fairly quickly, results which both WHO and IFPMA would consider a part of the Action Programme and of the 1982 industry commitment. Prudence would suggest a project involving only a few countries and only very few products. It should be possible from a group of maybe 35 to 40 least developed countries to select, say, five countries prepared to make a commitment to an action programme where some assurance can be obtained for distribution and prescription to the population in need--and for the necessary financial arrangements.

The assortment of products from each country should be developed in sufficient detail. Probably not more than ten drugs per country should be brought into the pilot project, but the specifications should ensure uniformity irrespective of which manufacturer actually undertakes the supply. The development implies uniform packaging and pack size, labeling using the logo of the Action Programme on Essential Drugs, the generic name of the products, as well as the name and address of the manufacturer. Specifications should preferably be developed to permit use of the same packs--if not labels--in several participating countries. The specifications are expected to give adequate information with a view to requirements for distribution, storage, and quality control, including bioavailability testing standards. In 1982 the United States Food and Drug Administration produced a list of 52 active drug ingredients which have documented bioavailability/bioequivalence problems.[1] Twenty of these substances appear on the WHO model list of essential drugs (1979).

The use of labels with the special logo of the Action Programme on Essential Drugs is important and shall serve, among other things, as a guard against leakages of drugs to unauthorized sources including the possibility that they may be sold for profit to neighbouring countries or even re-exported to the country from where they originally came.

## 13. Negotiating for Package Deals

Since prices for pharmaceutical products are determined through market conditions and competition, a logical step in the Action Programme on Essential Drugs is to enhance competition. The single most important element in such an effort would be to ensure market transparency. Ideally, a market intelligence unit should be at hand for obtaining, updating, and disseminating information on prices and price trends for products relevant to the programme. Valuable information is at hand from public tenders, such as the 1983 Tanzania tender, but also a wealth of information from the experience of UNICEF/UNIPAC and data bases operated by procurement organizations or control authorities in Member States might be utilized.

For a pilot scheme, as envisaged in this outline, the problem is not one of simply procuring certain drugs, but rather to enlist a cooperation for both drug supply and assistance to secure appropriate handling, warehousing, distribution, and management. Maybe even feasibility studies, equipment, and installations should be included--indeed, a package.

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[1] Scrip, 14 July 1982, page 14

The preparations for a package deal will be considerable. Analyses, forecasts, specifications of goods and services, guesstimates for the value of equipment installations or service components are together with the drug market intelligence output ultimately the basis for the assessment. Do we have an offer worthy of the term "non-commercial"?

A package of considerable complexity will undoubtedly be impractical for public tender--quite apart from the hints given by the industry of more attractive arrangements. The alternative to public tender is an active shopping around among selected potential suppliers. To say the least, this is a demanding job for a broker.

## 14. Ultimately a Commercial Basis

For the Action Programme on Essential Drugs , it is a vital consideration to determine for how long an offer of supply will be valid. Will the supplier deliver on the agreed terms for one year, for two years, or for five years? At any rate, non-commercial ties can hardly be expected to continue indefinitely from commercial enterprises. The problem is once a supply has been established--maybe over three years--for a population previously underserved, will there be at the end of the three years a purchasing power or other financial means to secure a continued supply on a commercial basis? A commercial basis may well be an international tender for generic drugs only and for products now well-known and well-established in the market; but a failure by the country and its advisers to forecast this ultimate stage might endanger the very purpose of the original effort.

## 15. A Fund for International Drug Procurement

This section reviews major options for the structure and operations of a Fund for International Drug Procurement, based on discussions held to date by WHO and UNICEF, on various expert studies, and on reports of recent country experiences. It is assumed that the desirable basic profile of a fund, whatever variations may eventually evolve, is summarized by the following features:

1. Facilitate the regular supply of essential drugs of acceptable quality at the PHC level at the lowest possible world market prices;

2. Enhance the process towards self-reliance in drug procurement of participating buying countries;

3. Establish its financial autonomy from initial capital endowment by recovering the full cost for services rendered; and

4. Attract additional sources of financing to expand the procurement scheme in response to needs for essential drugs.

### 15.1 Approach

The design of a viable structure for the contemplated Fund can be undertaken in normative terms by stating a series of requirements covering legal, organizational, managerial and financial aspects that would need to be

fulfilled to constitute and launch the Fund. Alternatively, the design - with allowance for major options in respect of critical factors - may be sketched in a more pragmatic manner having regard to current programmes and activities from which the Fund could evolve. This approach has been chosen here for the following reasons:

1. Choices available are linked to current practices and basic decisions by prospective participants more easily obtained;

2. Participation in the Fund is open-ended, essential features of its intended functions can be realized and demonstrated during an initial phase even in a one-country setting;

3. Early emphasis in respect of the Fund's structure and operational procedures can be appropriately placed on two key aspects: Finance and Prices, thus responding to primary concerns of prospective sponsors and buyer countries alike.

15.2 Essential Fund Functions

The benfits to be derived from a Fund scheme can easily be identified when viewing the drug supply system from the angle of the buying country, more precisely its central procurement agency(ies), whether or not only public sector requirements or also commercial transactions are channelled through the agency. In the latter case, the case for the Fund becomes even stronger, since the first type of benefit results from the ability to buy bulk, which provides leverage for exerting favourable price quotations and related payment as well as delivery terms from suppliers. The second advantage of strengthening the buyer's side in the market with focus on a restricted cluster of products from the list of essential drugs stems from the ability to establish an information system of reliable and interested suppliers as part of the Fund's procurement and, specifically, ordering strategy. Thirdly, the ability to negotiate the most advantageous terms while safeguarding product quality comes with financial standing and reputation, qualities which are more rapidly recognized in the international community if the Fund is well endowed. Most critical in this respect is the Fund's visibility as an institution whose instruments and operations protect it from liquidity problems and worse, eventual depletion. In present international economic and financial circumstances, it is only feasible to envisage a Fund structure meeting the above requirements with assets, liabilities and operations expressed and conducted in convertible currencies, preferably consolidated on a US dollar basis. Conversion to a base composed of Special Drawing Rights (SDRs) or a differently combined basket of convertible currencies remains a distinct possibility, depending on international monetary and exchange rate developments.

Finally, the Fund, after having established its record as a major international procurement mechanism for the reliable supply of essential drugs, will be in a position to encourage the build-up of facilities for production, packaging, transport, storage and distribution and related guarantee or insurance services where they are most economical in the longer-term perspective of satisfying the therapeutic needs of the large number of people who have yet to be brought into the orbit of primary health care services.

### 15.3 Sources of Financing

At the WHO Executive Board in January 1984 (EB73/18, para. 69) it was concluded that pool procurement benefitting several countries at a time was probably still some way off, but that international procurement arrangements based on annual turnover of considerable magnitude was a distinct and promising possibility. To be set in motion, one could envisage an extension of UNICEF's reimbursable purchase scheme. UNICEF/UNIPAC might then buy on behalf of a number of countries sub-quantities of a limited range of drugs, thus enabling them to obtain advantageous international prices. The capital required for starting operations could come from one or more of the following sources, taking account of both official declarations of intent and mere expressions of possible interest: WHO, UNICEF, World Bank, Regional Development Banks, UNDP, bilateral sources both donor and beneficial countries (e.g., national development and finance corporations), and non-governmental organizations including the pharmaceutical industry. Funding capital would be in the form of grants or equity, to be supplemented by long-term loans at concessional rates until the Fund had firmly taken hold.

Working capital could be obtained from official and private sources in the form of short-term suppliers', export, buyers' credit and adjacent guarantee/insurance facilities.

The funding volume required is a function of the volume of drugs to be procured over a given time span with proper allowance for ordering lead times, (re)packaging, transit and storage requirements and distribution paths. These elements determine the so-called procurement cycle which is symmetrical to the funds flow cycle.

## 16. What Next? - A List of Questions

As this paper deals with a variety of analytical and policy aspects, it may be useful to bring major issues into focus by raising a number of questions to which participants' reactions are invited. These questions - on the subject of procurement, pricing and funding - are attempts to clarify strategic choices. Which combination of steps and measures may be expected to benefit most rapidly and widely unserved rural and poor people in least developed countries that are striving to implement primary health care?

### 16.1 Procurement

From the angle of the buying countries, it appears that a prevailing majority of drugs required are multi-source, competitive items, and a minority are one-source (monopoly) items. Discussion might be focussed on the procurement, quite varying, of these contrasting groups of commodities. For proper buying of multi-source items, topics needing attention are:

1. The extent of centralization. Is it true that the level of price tends to be reversely proportional to the volume of purchasing?

2. The stabilization of supplies. Are long-term contracts always more favourable to the buyer, if prevailing price trends (at least over the last ten years) rather point downwards?

3. The choice of items. As long as funds (national and international) are insufficient for all the drugs needed, priority should go for items promising the largest bulk savings.

Annex 3.4



16.2 Pricing

As regards one-source items, little can be done along the above lines, considering the monopolistic position of suppliers and assuming their vertical power through distribution channels to dictate price conditions. Still, there is room for strategic choice:

4. What is the legal status of the drug, when is the price likely to come down? Within the period of patent validity, what is the price charged in various countries?

More generally, a monitoring system for enhanced market transparency could collect, process and disseminate information on competing quotations, relation between quotations and prevailing administered prices, the spread of the latter in various markets, and finally on payment, credit and delivery terms and conditions.

5. What are participants' views on the feasibility, organizational and technical characteristics of such a system or function to be added to existing structures?

A number of country experiences (Kenya, Tanzania, Gambia, Burundi, Haiti, Bhutan, etc.) may provide enough evidence to explore the feasibility and desirable features of cost recovery and cost-sharing formulas.

6. What are particpants' views on setting charges, particularly in the commercial sector and at hospital level, that enable cross-subsidization from higher to lower income groups and apart, from generating financial resources, help to put a cap on demand?

16.3 Funding

Experience to date with pooled procurement is not conclusive, but the experience with revolving fund arrangements - particularly in PAHO - is encouraging.

7. Participants may wish to comment on the proposed principles, structure and operational aspects of a Fund for International Drug Procurement.

8. What kind of safeguards and control down to which level would be required to ensure the Fund's expansion in response to countries' requests for services? An early warning system in respect of clients' liquidity problems and prompt measures to avoid a build-up of arrears in payment and ultimately write-offs of bad debt need to be designed.

Recent adjustment and stabilization programmes undertaken in some developing countries under the auspices of the International Monetary Fund include pledges from bilateral and multilateral sources for priority imports of basic needs requirements, including essential drugs. Some procurement has resulted in high-priced imports contradicting the very purpose of the IMF programme.

9. Could a Fund for International Drug Procurement not also perform this function of assuring best value for money procurement as part of IMF stabilization programmes by encouraging bilateral and multilateral financing agencies to entrust their contributions to the Fund?

The Fund should strengthen the capabilities of participating countries in a number of ways: Reallocate funds spent on costly items of less need to the procurement of essential drugs; ensure domestic and foreign exchange allocations from the national authorities in a framework of planned procurement linked to a sound and safe inventory policy; establish or improve the management tools of programme budgeting, costing and accounting, and monitor suppliers and prices. WHO/DAP has drafted a framework for evaluation of essential drug action programmes at country level covering these and other aspects.

10. Participants may wish to provide their views and suggestions on training facilities, materials, and curriculae so as to create and improve management skills in the above areas.

ANNEX 4

## LIST OF DOCUMENTS

1. Action Programme on Essential Drugs and Vaccines, DAP/84.4, World Health Organization, 1984

2. Global Medium-Term Programme, Essential Drugs and Vaccines, EDV/MTP/83.1, World Health Organization, 20 December 1983

3. Report of a Meeting on Drug Policies and Management: Guidelines for the Development of National Drug Policies, Geneva, 25-29 October 1982, DAP/83.6, World Health Organization, 1983

4. Essential Drugs Procurement, Example from Kenya: Ministry of Health: October 1983, Integrated Rural Health and Family Planning Programme, DAP/83.6, World Health Organization, 1983.

5. Action Programme on Essential Drugs. Report by the Executive Board Ad Hoc Committee on Drug Policies on behalf of the Executive Board, A35/7, World Health Organization, 1 April 1982

6. Country case: "Financing Essential Drugs in Bahrain" by Mohammed Jaffer Abdul Radha, Director of Materials Management, Ministry of Health, Bahrain

7. Country case: "The Mexican Experience on Procurement and Financing of Drugs and Vaccines in the Public Sector" by Dr Bernardo Sepulveda, Secretary of the General Council of Health, Mexico

8. Country case: Presentation on drug procurement in Sri Lanka by the State Pharmaceuticals Corporation by Dr Gladys Jayawardene, Chairman, State Pharmaceuticals Corporation of Sri Lanka

9. Remarks related to problems of financing and cost-sharing in pharmaceuticals. Presentation by Professor F. Lobo, General Director, Pharmacy and Health Products, Ministry of Health and Consumer Affairs, Spain

10. Discussion paper on Financing of Essential Drugs, by Arthur E. Shields, Assistant Director-General, Pharmaceutical Policy Branch Commonwealth Department of Health, Woden, A.C.T., Australia

11. "Procurement and Pricing of Drugs in Norway" by B. Joldal, Director, Directorate of Health, Pharmaceutical Department, Norway

12. "Major Issues Concerning Pharmaceutical Policies in the Third World" by Aurelie von Wartensleben, United Nations Conference on Trade and Development, Reprint Series No. 42 (from: World Development, Pergamon Press, Ltd, Vol. 11, No. 3 1983)

13. The selection, procurement, distribution, and use of pharmaceuticals in primary health care. From: Managing Drug Supply, pages 207-240, Management Sciences for Health, Boston, USA, 1981

14. Directory of Sources of Supply of Pharmaceutical Chemicals, Their Intermediates and Some Raw Materials Included in the UNIDO List Prepared by the UNIDO Secretariat, ID/WG.393/2/Rev. 1, 5 November 1984